UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION **THIS DOCUMENT RELATES TO:** **All Direct Purchaser Actions**	**Case No. 1:15-cv-07488-CM-RWL**

PLAINTIFFS' REVISED PROPOSED JURY INSTRUCTIONS

TABLE OF CONTENTS

PLAINTIFFS' PROPOSED JURY INSTRUCTIONS[1]

I. PRELIMINARY INSTRUCTIONS

A. General Instructions

Jury Instruction 1. Opening Instructions at Commencement of Trial[2]

We are about to begin the trial of the case you heard about during the jury selection. Before the trial begins, I am going to give you instructions that will help you understand what will be presented to you and how you should conduct yourself during the trial.

This trial involves the drug Namenda. Namenda "is a branded drug used to treat moderate to severe Alzheimer's, a neurogenerative brain disease that causes memory loss, among other symptoms."[3] The chemical name for Namenda is memantine hydrochloride. You will also hear it called memantine for short.

During the trial you will hear me use a few other terms that you may not have heard before. Let me briefly explain some of them to you. The parties who sue are called the plaintiffs. In this action, the Plaintiffs are JM Smith Drug Co. and Rochester Drug Co-Operative, Inc. The plaintiffs are wholesalers who purchase pharmaceuticals directly from manufacturers. They have brought this case as a class action.[4]

Let me explain what a class is. A group of individuals or companies that have similar legal claims can come together and file a lawsuit as a class. The court appoints representatives of the class to present the class's case. You will not hear from each individual member of the class, but

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[1] Plaintiffs reserve the right to add, delete, or modify these instructions to account for further developments in this case, such as new evidence and/or rulings from this Court or elsewhere.

[2] Cf. 3 FED. JURY PRAC. & INSTR. § 101:01 (6th ed.).

[3] *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 167 (S.D.N.Y. 2018) ("*Namenda V*").

[4] *Namenda V*, 331 F. Supp. 3d at 218.

your verdict will apply to the entire class.[5] Here the Class is a group of companies that directly purchased Namenda immediate release tablets, either 5 mg or 10 mg, and in either branded form or in generic form, or who purchased Namenda extended release tablets in branded form. You will hear Namenda immediate release referred to as "Namenda IR" and Namenda extended release as "Namenda XR".

The parties being sued are called the defendants. The Defendants here are Forest Laboratories, LLC, Actavis plc, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd. You may also hear during this trial that Actavis acquired a company called Allergan, Inc. For purposes of this trial, you do not need to make distinctions between the various Forest entities, Actavis and/or Allergan.

You will sometimes hear me refer to "counsel." "Counsel" is another way of saying "lawyer" or "attorney." I will sometimes refer to myself as the "Court."

[5] *See* Fed. R. Civ. P. 23; *Cooper v. Federal Reserve Bank of Richmond*, 467 U.S. 867, 874 (1984) ("a properly entertained class action is binding on class members in any subsequent litigation").

Jury Instruction 2. Plaintiffs' Claims

To help you follow the evidence, I will give you a brief summary of the positions of the parties.

Plaintiffs assert that Defendants violated the antitrust laws – laws passed by Congress to regulate competition. The purpose of the antitrust laws is to preserve free and unfettered competition in the marketplace. The antitrust laws rest on the central premise that competition produces the best allocation of our economic resources, the lowest prices, the highest quality, and the greatest material progress.[6]

Plaintiffs here are pursuing two theories of liability.

First, they assert that Defendants entered into an illegal agreement with another company called Mylan Pharmaceuticals, Inc. ("Mylan"). The agreement consists of several individual agreements. They are a "Settlement Agreement," a "License Agreement," and an "Amendment to Distribution and Supply Agreement (Generic Lexapro)" also known as the "Lexapro Amendment."

Mylan is not a defendant in this case. In a prior case, Defendants sued Mylan for alleged patent infringement relating to Mylan's generic version of Namenda IR.

The Defendants in this case settled their prior patent case against Mylan. The Plaintiffs here claim that that prior settlement violated the law because the Defendants paid Mylan to delay launching its generic Namenda IR until January 2015 or July 2015, which allowed Defendants to maintain their monopoly over memantine hydrochloride until the generic launched, and caused Plaintiffs and the Class to be overcharged. The exact date, whether January 2015 or July 2015,

[6] AM. BAR ASS'N MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES ("ABA MODEL INSTRUCTIONS"), Ch. 1, Instruction A-1.

depended on whether Defendants obtained an additional six months of exclusivity, known as pediatric exclusivity that you will hear about. Plaintiffs claim that Defendants paid Mylan through the Lexapro Amendment that you will hear about. When patent cases settle, they usually settle like most cases, with the defendant paying something to the plaintiff. However, here, Defendants, who were the plaintiffs in the patent case against Mylan, paid Mylan, who was the defendant in the patent case. The payment that is alleged went in the opposite or "reverse" direction of most payments when cases settle. That is why you may hear the payment called a "reverse payment." Plaintiffs here allege that Defendants' reverse payment to Mylan was in the form of payments conferred on Mylan under the Lexapro Amendment. Defendants dispute this claim.

As to this theory, you will first be asked to determine whether Defendants violated the antitrust laws and, if so, whether and when generic Namenda IR would have been available absent Defendants' conduct. Mylan is not a defendant here and you are not to concern yourself as to why.

Second, Plaintiffs assert they were injured as a result of conduct by Defendants known as a hard switch product hop. The "hard switch" refers to Defendants announcing they were going to withdraw Namenda IR from the market; and the "product hop" refers to Defendants converting the market from Namenda IR to Namenda XR. As to this theory, I instruct you that a court has already decided that Defendants violated the law, and that you must take it as established that Defendants' conduct publicizing their plan to discontinue Namenda IR and convert the market to Namenda XR was "coercive and anticompetitive" and that Defendants lacked "any non-pretextual procompetitive justification for its illegal conduct."[7] I instruct you that Defendants' hard switch product hop violated the law, starting with Defendants' February 14, 2014 public announcement

[7] *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-7488 (CM), 2017 WL 4358244, *16 (S.D.N.Y. May 23, 2017) (McMahon, J.) ("*Namenda IV*").

that Defendants would stop selling Namenda IR, which "*effectively withdrew*" Namenda IR from the market, and that "Defendants' hard switch – the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR – *forced* Alzheimer's patients who depend on memantine therapy to switch to [Namenda] XR[.]"[8] These issues were already decided in a prior lawsuit brought by the New York Attorney General and Defendants are not permitted to dispute them again.[9] As to Plaintiffs' claims regarding the hard switch product hop, you need to decide only if Plaintiffs paid some overcharge that was materially caused by the hard switch product hop, and if so, how much the overcharges were.[10] You must also decide the total overcharge damages, if any, suffered by the Direct Purchaser Class as a result of the reverse payment and delay in generic competition and the hard switch product hop combined.

I also instruct you that Defendants "possessed monopoly power over the U.S. memantine market up until the entry of generic competition" in July 2015.[11]

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[8] *Namenda IV*, 2017 WL 4358244, at *10 (citing *Namenda II*, 787 F.3d at 648, 654 (emphases added)).

[9] *Namenda IV*, 2017 WL 4358244, at *16 ("Plaintiffs' motion for collateral estoppel on these issues of fact is GRANTED. They will be presented to the jury as already decided.")

[10] *Namenda IV*, 2017 WL 4358244, at *17.

[11] *Namenda IV*, 2017 WL 4358244, at *16.

B. The Hatch-Waxman Act[12]

Jury Instruction 3. FDA Oversight of Drug Approvals

This case involves brand and generic drugs, and you will learn about how the United States Food and Drug Administration, or the "FDA" for short, approves drugs. Federal law requires that drug companies apply for and obtain approval from the FDA before they can sell a drug in this country.[13] I am going to give you a brief explanation of the drug approval process to help you understand better the evidence that will be presented.

[12] Similar instructions were given in the two pay-for-delay cases to proceed to trial since *Actavis*: *In re Nexium (Esomeprazole) Antitrust Litigation*, No. 12-md-2409, ECF 1439 (Dec. 3, 2014) (Transcript of Jury Charge); *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-cv-02768-MSG, ECF 1259 (July 6, 2017) (Final Jury Instructions) ("*Apotex* Final Jury Instructions").

[13] Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301-392; *F.T.C. v. Actavis*, 570 U.S. 536, 142 (2013).

Jury Instruction 4. Approval of Brand-Name Drugs

The first company to develop a particular drug files an application called a New Drug Application or "NDA."[14] The NDA contains technical information on the chemicals in the drug, the method of manufacturing it, and its effect on the human body.[15] The purpose of the NDA is to demonstrate to the FDA that the drug is safe and effective for its proposed uses.[16]

If the FDA concludes after reviewing the application that the drug is both safe and effective, it approves the New Drug Application and allows the drug to be sold in the United States.[17] Drugs approved under an NDA are often called "brand-name drugs" because manufacturers market them under a brand name rather than under the drug's chemical name. Namenda, the prescription drug at issue in this case, is an example of a brand-name drug. The active ingredient in both Namenda IR and Namenda XR is a chemical called memantine hydrochloride.

[14] Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), 21 U.S.C. § 355; *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 240 (3d Cir. 2017); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 711 (N.D. Ill. 2016).

[15] 21 U.S.C. § 355(b)(1); *Actavis*, 570 U.S. at 142.

[16] *Id.*; *New York ex. rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643 (2d Cir. 2017) ("*Namenda II*"); *Namenda V*, 331 F. Supp. 3d at 190.

[17] 21 U.S.C. § 355(c)(1)(A); *Actavis*, 570 U.S. at 142.

Jury Instruction 5. Generic Drugs

The FDA also approves generic drugs.[18] A generic drug is essentially the same as the brand-name drug: the generic drug must contain the same active chemical ingredient as the brand-name drug, must be in the same dosage form (*i.e.*, tablet or capsule) and in the same dosage strength as the brand-name drug, and must be bioequivalent to the brand-name drug.[19] But generic drugs are usually sold under their chemical name. If you buy Tylenol, for example, you are buying the brand name version. The active ingredient in Tylenol is acetaminophen. If you buy a bottle just labeled acetaminophen, it's the generic. The same goes for prescription drugs. Namenda and Namenda XR are the brand names; the generic is called memantine hydrochloride.

[18] 21 U.S.C. § 355(b)(1)(B); *Actavis*, 570 U.S. at 142.

[19] 21 U.S.C. § 355(j)(2); *Actavis*, 570 U.S. at 142.

Jury Instruction 6. The Hatch-Waxman Act

There is a federal law you will hear about that, among other things, governs how generic drugs are approved. Its full name is the "Drug Price Competition and Patent Term Restoration Act of 1984," but it is more commonly called the "Hatch-Waxman Act" or simply "Hatch-Waxman."[20] The Hatch-Waxman Act covers the requirements and procedures for approving generic drugs. As suggested by its full name, Hatch-Waxman was intended in part to encourage price competition between brand and generic manufacturers.[21] The Hatch-Waxman Act requires that the generic drug be essentially the same as the brand-name drug.

[20] 21 U.S.C. § 355.

[21] *Actavis*, 570 U.S. at 152 (referring to "the general procompetitive thrust" of Hatch-Waxman); *Namenda II*, 787 F.3d at 644 ("Hatch-Waxman also promotes competition from generic substitute drugs.").

Jury Instruction 7. Approval of Generic Drugs

A manufacturer gets FDA approval to market a generic drug by filing an Abbreviated New Drug Application,[22] also known as an "A-N-D-A," or an "ANDA." The generic manufacturer does not have to prove all over again that the drug is safe and effective, because the FDA has already found that the brand drug is safe and effective.[23] Generic drugs offer significant cost-savings, so Congress passed the Hatch–Waxman Act in order to provide an additional streamlined FDA approval process.[24] The generic manufacturer just needs to demonstrate that the generic drug is bioequivalent to the approved brand-name drug.[25] "Bioequivalent" means that the generic drug is absorbed in a person's body at the same rate and to the same extent as the brand-name drug.[26] The generic manufacturer must also prove that it can manufacture the drug to the required specifications.[27] These procedures ensure that a generic drug is as safe and effective as the brand. Once a generic manufacturer's proposed generic drug meets the FDA's requirements, the FDA

[22] 21 U.S.C. § 355(j)(2); *Actavis*, 570 U.S. at 142; *Lipitor*, 868 F.3d at 240; *Namenda II*, 787 F.3d at 644; *Opana*, 162 F. Supp. 3d at 711.

[23] *In re Lidoderm Antitrust Litigation*, 74 F. Supp. 3d 1052, 1058 (N.D. Cal. 2014) (*"Lidoderm MTD Order"*); *Namenda II*, 787 F.3d at 644.

[24] *Actavis*, 570 U.S. at 142 ("The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, 'speed[s] the introduction of low-cost generic drugs to market,' [*Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)], thereby furthering drug competition." (first alteration in original)); *Actavis*, 570 U.S. at 142 (noting that Hatch-Waxman allows "the generic manufacturer [to] obtain approval while avoiding the 'costly and time-consuming studies'" needed for approval of brand name drugs) (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).

[25] *Actavis*, 570 U.S. at 142 (citing *Caraco*, 566 U.S. at 405 and 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)); *Namenda II*, 787 F.3d at 644; *Namenda V*, 331 F. Supp. 3d at 191; *Opana*, 162 F. Supp. 3d at 711.

[26] 21 U.S.C. § 355(j)(8)(B).

[27] 21 U.S.C. § 355(j)(2)(A)(vi).

must grant the generic drug ANDA final approval – allowing the generic company to market its generic drug in the United States.

However, prior to receiving final FDA approval, a generic drug ANDA may sometimes obtain what is called "tentative" FDA approval. Tentative approval means that the FDA has determined that the generic drug meets all requirements for final FDA approval, but a regulatory or patent issue must be resolved first.[28] A generic may receive final approval without having to first obtain tentative approval.

[28] *Apotex Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1371 (Fed. Cir. 2015) ("Congress has defined 'tentative approval' to mean the FDA's determination that the ANDA has met the substantive requirements for obtaining generic marketing approval (by demonstrating, among other things, bioequivalence to the listed drug) but that final approval by the FDA is blocked by other barriers, such as a live patent, a 30-month stay caused by ongoing litigation, or certain exclusivity periods."); *Ranbaxy Labs., LTD v. Burwell*, 82 F. Supp. 3d 159, 188-189 (D.D.C. 2015) (the FDA interprets 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA) "as requiring the agency to grant tentative approval, instead of final approval, to an ANDA when the only reasons preventing final approval from being granted is a stay, some form of exclusivity, or existing patents," and "in the FDA's view, the requirements for tentative and final approval are identical, except that tentative approval does not require a showing that the ANDA will not infringe upon any valid patent.") (internal citations omitted); *Seattle Children's Hosp. v. Akorn, Inc.*, 2011 U.S. Dist. LEXIS 145998, *24-27, 2011 WL 6378838 (N.D. Ill. Dec. 20, 2011) ("The FDA grants 'tentative' approval when an ANDA meets all of the technical, safety and efficacy requirements for approval, but must await expiration of an exclusivity granted to another party.") (citing 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.107(b)(3)(v) (internal citations omitted)); *see also id.* (citing the FDA website, which notes that "[i]f a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, the FDA issues a tentative approval letter to the applicant.").

Jury Instruction 8. Competition Between Brand and Generic Drugs

The Hatch-Waxman Act also addresses how and when brand and generic drug companies can compete with each other. Brand-drug manufacturers often assert that their brand drug, or the process for making it, is covered by one or more patents.[29] You will be hearing about patents in this case. A patent is a document issued by the United States Patent and Trademark Office, or PTO, that describes an alleged invention. A patent may allow the patent holder to file a lawsuit seeking to exclude other manufacturers from making, using, offering to sell, or selling the claimed invention within the United States.[30] If a person or entity sells a product that is covered by a patent without the patent holder's permission, the patent holder can sue the seller for what is called "patent infringement." The person or entity sued has a number of potential defenses, including that the patent is not valid or that there is no infringement because the accused product is not covered by the patent.

I will explain more about patents later. For now, you simply need to understand that brand drug manufacturers often claim that sale of a competing generic drug would infringe one or more of the brand manufacturer's patents, while generic manufacturers often claim, in response, that their generic versions of brand drugs do not infringe or that the patents are not valid, or raise other defenses.

[29] *Actavis*, 570 U.S. at 143.

[30] 35 U.S.C. § 271.

Jury Instruction 9. The Orange Book

To promote challenges to patents relating to brand drugs, the Hatch-Waxman Act requires that a brand manufacturer filing a New Drug Application list all of its patents that it contends would be infringed by the sale of a competing generic.[31] The list is kept in an FDA publication called the "Orange Book."[32] It is called that because the original print version years ago had an orange cover. By putting the patents in the Orange Book, the FDA is not making any judgments about whether the patents are valid or would be infringed by a generic product. The FDA simply lists the patents that the brand drug manufacturer asks it to list.[33]

[31] 21 U.S.C. § 355(b)(1).

[32] The term "Orange Book" refers to the FDA's publication formally titled "Approved Drug Products with Therapeutic Equivalence Evaluations" and specifically its Patent and Exclusivity Information Addendum, which FDA is required to update every 30 days. 21 U.S.C. § 355(j)(7)(A); *Lipitor*, 868 F.3d at 240; *Opana*, 162 F. Supp. 3d at 711.

[33] *In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) ("the FDA is required by law to publish the information in the Orange Book. *See* 21 U.S.C. §§ 355(b)(1) & (c)(2) ('Upon submission of patent information under [these] subsection[s], the Secretary shall publish it.'). Hence, the FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing."); *Lipitor*, 868 F.3d at 240 ("the FDA publishes the submitted patent information"); *Opana*, 162 F. Supp. 3d at 711 (Orange Book contains patents "that the manufacturer believes could reasonably be asserted against" a generic manufacturer).

Jury Instruction 10. Paragraph IV Certification

When a generic manufacturer submits an ANDA seeking FDA approval to market a generic version of the brand drug, the Hatch-Waxman Act requires the generic manufacturer to make one of four certifications regarding the patents that the brand manufacturer has listed in the Orange Book concerning the drug.[34] The particular type of patent certification involved in this case is known as a "Paragraph IV Certification."[35] In a Paragraph IV Certification, the generic manufacturer certifies that, although the brand manufacturer has listed certain patents in the Orange Book with respect to the brand drug, selling the generic drug before those brand patents expire will not infringe the patents or that the patents are not valid.[36] A generic manufacturer making a Paragraph IV certification must notify the brand manufacturer of the generic manufacturer's Paragraph IV certification.

[34] 21 U.S.C. § 355(b)(2)(A); *Actavis*, 570 U.S. at 142-43; *Lipitor*, 868 F.3d at 240-41; *Opana*, 162 F. Supp. 3d at 711.

[35] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[36] *Id.*; *Lidoderm MTD Order*, 74 F. Supp. 3d at 1060; *Actavis*, 570 U.S. at 143.

Jury Instruction 11. Stay of FDA ANDA Approval

If the brand company brings patent infringement litigation against a generic company in federal court within 45 days after receiving notice of the Paragraph IV Certification from the generic company, final approval of the ANDA by the FDA is stayed, or postponed, under the Hatch-Waxman Act. This stay is typically 30 months long.[37]

[37] Ordinarily, the Hatch-Waxman Act provides for a five-year marketing exclusivity period for a brand-name drug with an active ingredient that qualifies as a new chemical entity (NCE). During this five-year period, ANDAs cannot be filed. That period is reduced to four years if the ANDA application includes a Paragraph IV Certification. 21 U.S.C. § 355(j)(5)(F)(ii). In the event that a Paragraph IV ANDA is filed at the end of the four-year period and a lawsuit is commenced within forty-five days of the receipt of the Paragraph IV notice, the Hatch-Waxman Act requires that the 30-month stay be "extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval" of the NDA. *Id.*

Jury Instruction 12. Purpose of the Hatch-Waxman Act

In passing the Hatch-Waxman Act, Congress wanted, among other purposes, to encourage generic manufacturers to challenge the validity, enforceability, and applicability of brand patents.[38] Congress understood both that some brand patents are invalid or unenforceable and that generic companies can develop generics that do not infringe the patents even if they are valid and enforceable.

[38] *See Actavis*, 570 U.S. at 143 ("[T]he Hatch-Waxman Act sets forth special procedures for identifying, and resolving, patent disputes."); *Lipitor*, 868 F.3d at 241 (Hatch-Waxman provides 180-day exclusivity [discussed below] to "incentivize generic drug manufacturers to file an ANDA challenging weak patents"); *Opana*, 162 F. Supp. 3d at 711 (180-day exclusivity is "an incentive for generic pharmaceutical companies to challenge suspect patents listed in the Orange Book").

Jury Instruction 13. 180-Day Exclusivity

Congress wanted to give generic drug companies a financial incentive to do the work needed to challenge brand drug patents and demonstrate that the patents are invalid or unenforceable, or invent around them, which means developing a generic that does not infringe.[39] So Congress created a reward to encourage generic manufacturers to challenge brand patents.[40] You will hear the lawyers and witnesses refer to this reward as the "180-day exclusivity." Here is how it works. The first generic manufacturer that files a Paragraph IV Certification with respect to a particular brand drug can get a period of 180 days during which it is the only company allowed to sell a generic version of that brand drug in the United States, with certain important exceptions I will explain in a moment.[41] The Hatch-Waxman Act prohibits the FDA from granting approval of any other manufacturer's ANDA for that same drug until 180 days after the first generic manufacturer that filed a Paragraph IV Certification has entered the market.[42]

I said there were important exceptions. The first is that if two generic companies, or three, or however many there are, all are "first" to file a Paragraph IV Certification, like a race than ends in a tie, then all the generic companies can launch during that first 180 days, although no later ANDA filers would be permitted to.

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[39] H.R. REP. NO. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[40] *Id.*

[41] 21 U.S.C. § 355(j)(5)(B)(iv)(I), § 355(j)(5)(D)(i)(I); *Actavis*, 570 U.S. at 143; *Lipitor*, 868 F.3d at 241; *Opana*, 162 F. Supp. 3d at 711.

[42] 21 U.S.C. § 355(j)(5)(B)(iv)(I); *Actavis*, 570 U.S. at 144; *Lipitor*, 868 F.3d at 241; *Opana*, 162 F. Supp. 3d at 711.

Jury Instruction 14. Authorized Generics

The second important exception is that the 180-day exclusivity period only prevents the FDA from granting approval to any other manufacturer's *ANDA* during that period. The 180-day exclusivity does *not* apply to the brand company itself. The brand company can keep selling its own brand drug during the 180-day period and afterwards.[43] A brand company can also sell what is called an "authorized generic."[44] An authorized generic is the brand drug, sold by the brand company or by another company that the brand company authorizes, but with a generic label and usually at cheaper generic prices. The brand can sell an authorized generic whenever it wishes to, including during the 180-day exclusivity period.[45]

[43] *Opana*, 162 F. Supp. 3d at 711 ("During the 180-day period of market exclusivity, the first-filer only competes against the brand manufacturer and potentially any Authorized Generic ('AG') marketed under the brand manufacturer's NDA").

[44] *Teva Pharm. Indus. v. FDA*, 410 F.3d 51, 54 (D.C. Cir. 2005); 21 U.S.C. § 355(t)(3).

[45] *In re Lipitor Antitrust Litig.*, 855 F.3d 126, 135-36 (3d Cir. 2017) ("Hatch–Waxman does not preclude the underlying patent-holder from marketing a brand-generic version of its drug—known as an 'authorized generic'—during the 180–day exclusivity period") (collecting cases).

Jury Instruction 15. Pediatric Exclusivity

In addition to possible periods of patent protection, brand manufacturers are also sometimes entitled to certain regulatory exclusivities. One such exclusivity is called a Pediatric Exclusivity. In accordance with legislation, the FDA may request that brand manufacturers perform studies of certain effects of a particular drug on pediatric populations. If the brand manufacturer submits a study as the FDA requests and approves, then the FDA may award the brand manufacturer six months of pediatric marketing exclusivity.[46] The six-month period begins on the date that the existing patent or regulatory exclusivity listed by the brand manufacturer in the Orange Book would otherwise expire.[47] The six-month Pediatric Exclusivity is a regulatory exclusivity, not an extension of any patent or any other exclusivity.[48]

[46] 21 U.S.C. §§ 355a(b), §355a(c).

[47] *See* Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act: Frequently Asked Questions on Pediatric Exclusivity (505A) at A9, available at: https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm077915.htm.

[48] 21 U.S.C. §§ 355a(b), §355a(c); *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1343 (Fed. Cir. 2015)

C. Patents

Jury Instruction 16. Definition of Patent

The Hatch-Waxman Act addresses how and when brand and generic drug companies can compete with each other. Brand-drug manufacturers often assert that the approved use of the brand drug is covered by one or more patents. If a court finds a patent to be "valid" and "infringed" – concepts that I will address in a moment – the court can order the infringer not to make, use, or sell the accused product until the patent expires.[49] If, however, the court finds the patent is invalid or not infringed, the patent holder is not entitled to keep the accused product out of the market.

In this case, Defendants claimed that U.S. Patent No. 5,061,703, which you will hear called the "'703 patent" for short, entitled them to exclude competitors from marketing a memantine hydrochloride product in the United States. The Defendants licensed the '703 patent from a German pharmaceutical company called Merz + Co. GmbH & Co. ("Merz"). Merz is not a defendant in this case and you are not to concern yourself as to why.

[49] 35 U.S.C. § 271(e)(4)(A).

Jury Instruction 17. Patent Specification and Claims

To get a patent, an applicant files an application with the PTO. The application includes what is called a "specification," which contains a written description of the alleged invention explaining what the alleged invention is, how it works, how to make it, and how to use it.[50] The specification concludes with one or more patent claims, each of which is a single, numbered sentence.[51] A patent claim that refers back to an earlier claim is called a "dependent claim" and incorporates all of the requirements of the earlier claim. If the PTO eventually grants a patent to the applicant, the patent claims define the boundaries of the alleged invention and give notice to the public of what is covered by the patent.[52]

Employees of the PTO called "patent examiners" review all patent applications to determine whether or not the alleged inventions set forth in the patent claims are appropriate for patenting.[53] Examiners review what is called "prior art," which includes knowledge that existed before the claimed invention, such as patents and scientific publications from any country.[54] The examiner considers, among other things, whether each claim defines an invention that is new, useful, and not obvious in view of the prior art.[55]

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[50] 35 U.S.C. § 112.

[51] 35 U.S.C. § 112(b).

[52] *Id.*

[53] 35 U.S.C. § 271; 35 U.S.C. § 102.

[54] Federal Circuit Bar Association Model Patent Jury Instructions A.1.

[55] Federal Circuit Bar Association Model Patent Jury Instructions A.1.

Jury Instruction 18. Patent Application Process

After evaluating the application,[56] the examiner informs the applicant in writing of what the examiner has found and whether the examiner considers any claim to be patentable and, thus, "allowed." If the examiner instead "rejects" the claims,[57] the applicant has an opportunity to respond to the examiner to try to persuade the examiner to allow the claims as stated, to change the claims, or to submit new claims.[58] This process is called patent prosecution and may go back and forth and continue until the examiner concludes either that the patent claims in the application meet the requirements for a patent and the PTO should issue the patent, or that the patent claims in the application do not meet the requirements and the PTO should not issue the patent.[59] The correspondence back and forth between the examiner and the patent applicant make up what is called the "prosecution history."

When the patent applicant is trying to obtain a patent, there is no one on the other side, opposing the applicant. It's not like here in court, where you will hear lawyers and witnesses for both sides. When the PTO is examining a patent application, there is no one arguing that the PTO should not issue the patent. The process is conducted without an adversary arguing against what the applicant is telling the examiner.[60]

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[56] 37 CFR 1.104(a)(1); Manual of Patent Examining Procedure ("MPEP") §§ 704.01, 707(a)(1).

[57] 35 U.S.C. § 132; MPEP § 704.01(c).

[58] 35 U.S.C. § 132.

[59] 37 CFR 1.104(a)(1); MPEP § 707(a)(1).

[60] 37 CFR § 1.902-1.997 (providing for *inter partes* review of patents only post-issuance).

Jury Instruction 19. Reexamination

After a patent is issued, it can be "reexamined." Reexamination is a process in which the PTO determines whether one or more of the claims are patentable with respect to specifically-identified prior art consisting of prior patents or printed publications.[61] An "ex parte" reexamination is a particular type of reexamination that can be initiated by the patent holder and does not include the participation of any third party.[62] Any patent claims resulting from a reexamination proceeding cannot be broader in any respect than the patent's originally-issued claims; if the reexamined claims are broader in any respect than the originally-issued claims, then they are invalid.[63] In this case, the '703 patent was subject to an ex parte reexamination.

[61] N.D. Cal. Model Patent Instructions 2017.

[62] N.D. Cal. Model Patent Instructions 2017.

[63] *Predicate Logic, Inc. v. Distributive Software, Inc.*, 544 F.3d 1298, 1302 (Fed. Cir. 2008) ("Under 35 U.S.C. § 305, '[n]o proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding.' Claims that are impermissibly broadened during reexamination are invalid, and 'a violation of 35 U.S.C. § 305 is an invalidity defense in a patent infringement action.'").

Jury Instruction 20. The Patent Application Process is not an Adversary Proceeding

Because patents are obtained and can be reexamined in an ex parte process without the participation of third parties such as the patent owner's competitors, Congress provided in the patent laws that a patent or reexamination certificate issued by the PTO can be challenged later in federal court. A patent holder who wants to enforce its patent against competitors can bring a lawsuit in federal court, but in a court unlike in the PTO, the patent holder faces an adversary who can present the other side of the argument.[64]

[64] *Id;* 35 U.S.C. § 281; 28 U.S.C. § 1338.

Jury Instruction 21. Infringement of Patents

In this case, the '703 Patent claimed methods of using certain drugs including memantine. In patent lawsuits, the patent holder has the burden of proving by a preponderance of the evidence that at least one patent claim covers the accused infringer's method.[65]

I will explain this again after all the evidence is in, but preponderance of the evidence is same standard that applies generally to Plaintiffs' claims here as well. It does not require proof to an absolute certainty, since proof to an absolute certainty is seldom possible in any case. "Establish by a preponderance of the evidence" means evidence, which as a whole, shows that the fact sought to be proved is more probable than not.[66]

You may have heard of the term "proof beyond a reasonable doubt." That is a stricter standard applicable in criminal cases. It does not apply in civil cases such as this nor does it apply in patent cases. You should, therefore, put it out of your minds.[67]

When a patent claim covers the accused method, this is called "infringement."[68] To prove infringement, the patent holder must prove that the accused infringer performs each part of an asserted patent claim or that the accused infringer actively induced a third party to perform each part of the claim.[69] A dependent claim cannot be infringed if the claim it depends from is not

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[65] *Under Sea Industries, Inc. v. Dacor Corp*., 833 F.2d 1551, 1557 (Fed. Cir. 1987) ("The burden always is on the patentee to show infringement").

[66] 3 FED. JURY PRAC. & INSTR. § 104:01 (6th ed.) (modified).

[67] *Id.*

[68] 35 U.S.C. § 271(a).

[69] *Pennwalt Corp. v. Durand-Wayland, Inc*., 833 F.2d 931, 935-36 (Fed. Cir. 1987) (en banc), *overruled on other grounds*, *Cardinal Chem. Co. v. Morton Intern., Inc*., 508 U.S. 83 (1993); Federal Circuit Bar Association Model Jury Instructions B.3.2.

infringed.[70] If the patent holder fails to meet its burden of proving infringement, then the accused infringer wins the lawsuit. Although a person accused of infringement has no burden of proof regarding infringement, it nevertheless has the right to present evidence, including expert evidence, to refute the patent holder's allegation of infringement.[71] In addition, an invalid patent cannot be infringed because that means there is no patent to infringe.[72] I will discuss patent invalidity next.

[70] *Wahpeton Canvas Co. v. Frontier, Inc*., 870 F.2d 1546, 1553 (Fed. Cir. 1989) ("It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed. . . .")

[71] 35 U. S. C. § 282(b)(1).

[72] *Commil USA, LLC v. Cisco Sys.*, 135 S.Ct. 1920, 1929 (2015) ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics. . . . [A]n act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

Jury Instruction 22. Invalidity of Patents

Even if the patent holder carries its burden of proving infringement of one or more of the patent's claims, the accused infringer can still win the patent case by proving that any infringed claims are invalid.[73] Although an issued patent is presumed to be valid, the fact that the PTO grants a patent does not necessarily mean that any invention claimed in the patent, in fact, deserves the protection of a patent.[74] For example, the PTO may not have had available to it all the information and other evidence that would be available in a federal court proceeding.[75] A person accused of infringement has the right to argue in federal court that a claimed invention in the patent is invalid because it does not meet the requirements for a patent.

To prove invalidity of a patent claim, an accused infringer must provide clear and convincing evidence.[76] A patent claim is invalid if, for example, the claimed invention is not new or if the claimed invention would have been obvious to a person of ordinary skill in the field at the time the patent was filed.[77] Clear and convincing evidence means evidence "sufficient to give you an abiding conviction that its correctness is highly probable."[78] It is a higher standard than preponderance of the evidence, and lower than beyond a reasonable doubt.

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[73] 35 U. S. C. §282(b)(2).

[74] Federal Circuit Bar Association Model Patent Jury Instructions A.1.

[75] Federal Circuit Bar Association Model Patent Jury Instructions A.1.

[76] Federal Circuit Bar Association Model Patent Jury Instructions B.4.1.

[77] Federal Circuit Bar Association Model Patent Jury Instructions B.4.3b-1, B.4.3c.

[78] *Price v. Symsek*, 988 F.2d 1187, 1191 (Fed. Cir. 1993) ("A requirement of proof by clear and convincing evidence imposes a heavier burden upon a litigant than that imposed by requiring proof by preponderant evidence but a somewhat lighter burden than that imposed by requiring proof beyond a reasonable doubt. Clear and convincing evidence has been described as evidence which produces in the mind of the trier of fact an abiding conviction that the truth of a factual contention is highly probable.") (internal citations and quotations omitted); *Impax Labs. Inc. v. Lannett Holdings Inc.*, 893 F.3d 1372, 1378 (Fed. Cir. 2018) ("A party challenging the validity

If the claimed method in the patent has been previously disclosed to the public, then it is not new, and therefore the claimed invention is invalid as "anticipated" by the prior disclosure.[79] Simply put, the invention must be new to be entitled to patent protection under the U.S. patent laws.[80] To anticipate a claim, each and every element in the claim must be present in a single item of prior art.[81] In determining whether the single item of prior art anticipates a patent claim, it is important to consider not only what is expressly disclosed in the particular prior art reference but also what is inherently present or disclosed in that prior art or inherently results from its practice.[82] Prior art inherently anticipates a patent claim if an element of the claim that is not expressly disclosed by the prior art would necessarily result from what the single item of prior art teaches to persons of ordinary skill in the art.[83] Evidence outside of the prior art reference itself may be used to show that elements that are not expressly disclosed in the reference are inherent in it.[84] In order to be inherent, the feature that is alleged to have been inherent must necessarily have existed in the prior art reference or have been the natural result of the prior art.[85] It is not required, however, that persons of ordinary skill actually recognize or appreciate the inherent disclosure at the time the

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of a patent must establish invalidity by clear and convincing evidence. Clear and convincing evidence should place[ ] in the fact finder an abiding conviction that the truth of [the] factual contentions are highly probable.") (internal citations and quotations omitted); *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988) ("Although not susceptible to precise definition, 'clear and convincing' evidence has been described as evidence which produces in the mind of the trier of fact 'an abiding conviction that the truth of [the] factual contentions are highly probable.'").

[79] 2017 AIPLA Model Patent Jury Instructions 6.0.

[80] 2017 AIPLA Model Patent Jury Instructions 6.0.

[81] 2017 AIPLA Model Patent Jury Instructions 6.0.

[82] 2017 AIPLA Model Patent Jury Instructions 6.0 (modifications to reflect this case).

[83] 2017 AIPLA Model Patent Jury Instructions 6.0.

[84] 2017 AIPLA Model Patent Jury Instructions 6.0.

[85] 2017 AIPLA Model Patent Jury Instructions 6.0.

prior art was first known or used.[86] Thus, the prior use of the patented invention that was unrecognized and unappreciated is still an invalidating anticipation, provided the allegedly inherent feature was necessarily present in the prior art reference.[87]

In addition, if the prior art describes a group or genus, which is a Latin word meaning a general class, and that genus is so limited that a person of ordinary skill can readily envision each member of the genus, then the prior art is said to anticipate every member within the genus.[88] In other words, the disclosure of a group in a prior art reference may anticipate a member of that group even if the members of the group are not themselves expressly stated in the prior art.[89]

A claimed invention is invalid as "obvious" if it would have been obvious to a person of ordinary skill in the art of the claimed invention at the time the invention was made.[90] Unlike anticipation, which allows consideration of only one item of prior art, obviousness may be shown by considering one or more than one item of prior art.[91] The following factors must be evaluated to determine whether an accused infringer has established that the claimed subject matter is obvious:[92]

1. the scope and content of the prior art;
2. the difference or differences, if any, between the claimed subject matter and the prior art;

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[86] 2017 AIPLA Model Patent Jury Instructions 6.0.

[87] 2017 AIPLA Model Patent Jury Instructions 6.0.

[88] *In re Gleave*, 560 F.3d 1331, 1338 (Fed. Cir. 2009); *see also Eli Lilly and Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1376 (Fed. Cir. 2006); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005)).

[89] *Bristol–Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001).

[90] 2017 AIPLA Model Patent Jury Instructions 7.0.1.

[91] 2017 AIPLA Model Patent Jury Instructions 7.0.1.

[92] 2017 AIPLA Model Patent Jury Instructions 7.0.1.

3. the level of ordinary skill in the art at the time the invention; and

4. additional considerations, if any, that indicate that the invention was obvious or not obvious.

For purposes of determining whether there are any relevant differences between the prior art and the claimed subject matter, inherent disclosures of the prior art must also be considered.[93]

[93] *See* 2017 AIPLA Model Patent Jury Instructions 7.2.1.

Jury Instruction 23. Enablement

The accused infringer may also show that the claims in the patent are invalid because they are not enabled. A patent's specification must contain a sufficiently full and clear description of how to make and use the invention.[94] To be sufficiently full and clear, the description must contain enough information to have allowed a person having ordinary skill in the field of technology of the patent to make and use the full scope of the claimed invention at the time the patent application was filed.[95] Moreover, where a patent claim relates to a method of treatment, the enablement requirement is not satisfied unless a person skilled in the art would accept without question the claimed effects of the drug.[96] This is known as the "enablement" requirement. If a patent claim is not enabled, it is invalid.

[94] Federal Circuit Bar Association Model Patent Jury Instructions B.4.2b.
[95] Federal Circuit Bar Association Model Patent Jury Instructions B.4.2b.
[96] *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005).

Jury Instruction 24. Patent Term Extensions

Patents are only enforceable for a set length of time, referred to as the patent's term. A patent's term can sometimes be extended by showing that a drug covered by the patent was subject to regulatory review before its commercial marketing or use.[97] In order to obtain a patent term extension, the patent holder or its agent must submit an application containing certain information to the PTO.[98] An applicant for a patent term extension is only entitled to an extension for times when the applicant was diligently working towards obtaining FDA approval for the drug. The application must provide (1) the number of days during the regulatory review period during which it was not diligently pursuing approval; and (2) a description of the clinical work done during the regulatory review period.[99] When submitting the application, the patent holder and its agent owe a duty of candor and good faith and must disclose all material information.[100] Only the Director of the PTO can decide whether a patent term should be extended, and the Director may do so solely on the basis of the representations in the application.[101] Although an issued patent term extension is presumed to be valid, the presumption can be overcome by clear and convincing evidence. Specifically, part or all of a patent term extension is invalid if there was a material failure by the applicant to comply with the requirements for obtaining the patent term extension.[102]

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[97] 35 U.S.C. § 156(a)(4).
[98] 35 U.S.C. § 156(d)(1)(C).
[99] 37 C.F.R. § 1.775(d)(1)(ii); 35 U.S.C. § 156(d).
[100] 35 C.F.R. § 1.765.
[101] 35 U.S.C. §156(e)(1).
[102] 35 U.S.C. § 282.

Jury Instruction 25. Decisions in Patent Lawsuits

If the patent holder proves infringement and the accused infringer fails to prove that the patent is invalid, then the patent holder wins the patent lawsuit.[103] If, however, the patent holder fails to prove infringement and/or the accused infringer proves that the patent is invalid, then the accused infringer wins the lawsuit. In that event, the accused infringer can begin selling the product without any risk of owing damages to the patent holder. Moreover, if the patent is found invalid, it is invalid as to all companies, period, and therefore no longer prevents any company from competing. Further, irrespective of whether the accused infringer prevails on infringement and validity, if the accused infringer succeeds in challenging a patent term extension, the accused infringer can enter the market based on the original expiration date of the patent or, if some portion of the patent term extension is valid, after that period expires.

[103] 35 U.S.C. § 282.

Jury Instruction 26. Patent Lawsuits under the Hatch-Waxman Act

These basic principles of patent law work together with the specific Hatch-Waxman Act provisions that I already described to you. For example, recall these specific provisions of the Hatch-Waxman Act that are applicable to the pharmaceutical patents that are in the background of this antitrust case: (1) the brand manufacturer must list a relevant patent in the Orange Book;[104] (2) the generic manufacturer can file a Paragraph IV Certification with respect to it;[105] (3) the brand manufacturer can get an automatic stay preventing the FDA from approving the generic drug for 30 months by suing the generic within 45 days;[106] (4) the first generic manufacturer to file a Paragraph IV Certification can get the 180-day ANDA exclusivity, and if multiple generic companies all file at the same time and all are "first," they all share the 180-day period; and (5) the 180-day exclusivity cannot stop a brand company from selling its own authorized generic at any time.[107]

Within this specific framework, the general patent principles that I have just outlined apply: the PTO issues patents in an ex parte process where only one side, the side that wants the patent, is presenting arguments; to enforce the patent, the patent holder can bring a lawsuit in federal court where the patent is subject to challenge;[108] in that lawsuit the patent holder has the burden of proving infringement;[109] the accused infringer can defend the lawsuit on the basis that there is no

[104] 21 U.S.C. § 355(b)(1).

[105] 21 U.S.C. § 355(b)(2)(A); 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[106] 21 U.S.C. § 355(c)(3)(C).

[107] 21 U.S.C. § 355(j)(5)(B)(iv)(I).

[108] 35 U.S.C. § 281; 28 U.S.C. § 1338.

[109] *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987).

infringement, the patent is invalid, or that part or all of any patent term extension is invalid;[110] if the patent holder wins, it can ask the court to prevent the accused infringer from making, using, or selling the product and, if the accused infringer has already entered the market, can ask for damages; if the accused infringer wins, it can enter in the market without any risk of patent damages or stay on the market if it had already entered; and if the accused infringer wins by proving that the patent is invalid, that finding of invalidity benefits everyone who wants to make, use, or sell the product.[111]

[110] 35 U.S.C. § 282(b)(2).

[111] *Blonder-Tongue Lab. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971).

II. INSTRUCTIONS FOR CONCLUSION OF TRIAL

A. General Instructions

Jury Instruction 27. General Introduction [After the Evidentiary Record is Closed]

Now that you have heard the evidence and the arguments, it is my duty to instruct you about the applicable law. It is your duty to follow the law as I state it. You must apply the law to the facts as you find them from the evidence in the case. Do not single out one instruction as stating the law, but consider the instructions as a whole. Do not be concerned about the wisdom of any rule of law stated by me. You must follow and apply the law.

The lawyers have referred to some of the governing rules of law in their arguments. If there is any difference between the law stated by the lawyers and these instructions, you must follow my instructions.

Nothing I say in these instructions indicates I have any opinion about the facts. You, not I, determine the facts.

You must perform your duties as jurors without bias or prejudice as to any party. The law does not permit you to be controlled by sympathy, prejudice, or public opinion. All parties expect that you will carefully and impartially consider all the evidence, follow the law as it is now being given to you, and reach a just verdict, regardless of the consequences.

3 FED. JURY PRAC. & INSTR. § 103:01 (6th ed.)

Jury Instruction 28. Preponderance of the Evidence

Plaintiffs have the burden in a civil action, such as this, to prove every essential element of Plaintiffs' claim by a preponderance of the evidence. If Plaintiffs fail to establish any essential element of Plaintiffs' claim by a preponderance of the evidence, you should find for Defendants as to that claim.

As I explained at the start, this standard does not require proof to an absolute certainty, since proof to an absolute certainty is seldom possible in any case. "Establish by a preponderance of the evidence" means evidence, which as a whole, shows that the fact sought to be proved is more probable than not. In other words, a preponderance of the evidence means such evidence as, when considered and compared with the evidence opposed to it, has more convincing force, and produces in your minds belief that what is sought to be proved is more likely true than not true.

In determining whether any fact in issue has been proved by a preponderance of the evidence, unless otherwise instructed you may consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

The Defendants have the burden of establishing the essential elements of certain affirmative defenses. I will explain this later.

You may have heard of the term "proof beyond a reasonable doubt." That is a stricter standard applicable in criminal cases. It does not apply in civil cases such as this. You should, therefore, put it out of your minds.

3 FED. JURY PRAC. & INSTR. § 104:01 (6th ed.) (modified)

Jury Instruction 29. Evidence in the Case

The evidence in the case consists of the following:

1. The sworn testimony of the witnesses, either called live or by videotape, no matter who called a witness.
2. All exhibits received in evidence, regardless of who may have produced the exhibits.
3. All facts that I instruct you must take as true for purposes of this case.

You heard depositions played on videotape. Depositions contain sworn testimony, with the lawyers for each party being entitled to ask questions. Deposition testimony should be considered by you just as if the testimony was live in court, subject to the same instructions that apply to witnesses testifying in open court.

Statements and arguments of the lawyers are not evidence, unless made as an admission or stipulation of fact. A "stipulation" is an agreement between both sides that certain facts are true or that a person would have given certain testimony. When the lawyers on both sides stipulate or agree to the existence of a fact, you must, unless otherwise instructed, accept the stipulation as evidence, and regard that fact as proved.

[*If applicable*: I have taken judicial notice of certain facts or events. When I declared that I took judicial notice of some fact or event, you must accept that fact as true.]

Some evidence was admitted for a limited purpose only. When I instructed you that an item of evidence had been admitted for a limited purpose, you must consider it only for that limited purpose and for no other purpose.

You are to consider only the evidence in the case. But in your consideration of the evidence, you may draw from the facts that you find have been proved, such reasonable inferences or conclusions as you feel are justified in light of your experience.

3 FED. JURY PRAC. & INSTR. § 101:44 (6th ed.) (modified)

Jury Instruction No. 30. Requests to Rehear Testimony

Now, if it should happen during deliberations that you want to hear any of the testimony again, we can do that. Send out a note, signed by the foreperson, telling us what you want to hear. Be as specific as you can when you ask because you don't want us to send you back 60 pages of testimony when you really only want one little bit. Most likely we will send the testimony back to you because we have the transcript. Or we might choose to bring you out here and let you listen to it again if it is a videotape deposition.

Now, please make sure that you exhaust your collective memory before you ask for a read back of testimony. All of you putting your heads together will remember more than any one person possibly can. But if after your discussion you're in doubt or you're vague about what the transcript shows, just send out a note. We will drop everything and make sure that that testimony is conveyed to you.

Jury Instructions, Trial Tr. May 11, 2010 at 3565-66, *Velez v. Novartis Pharms. Corp*., No. 04 Civ. 9194 (S.D.N.Y.) (McMahon, J.) (modified).

Jury Instruction 30. What is Not Evidence

In deciding the facts of this case, you are not to consider the following as evidence: statements and arguments of the lawyers, questions and objections of the lawyers, testimony or exhibits that I instructed you to disregard, any evidence that I ordered stricken, and anything you may see or hear when the court is not in session—even if what you see or hear is done or said by one of the parties or by one of the witnesses. If I sustained an objection to a question or the admission of an exhibit, you must ignore the question and must not guess what the answer to the question might have been or what the exhibit might have said.

3 FED. JURY PRAC. & INSTR. §§ 101:44; 101:49 (6th ed.) (modified)

Jury Instruction 31. Direct and Circumstantial Evidence

"Direct evidence" is direct proof of a fact, such as testimony by a witness about what the witness said or heard or did. "Circumstantial evidence" is proof of one or more facts from which you could find another fact. You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. You are to decide how much weight to give any evidence.

3 FED. JURY PRAC. & INSTR. § 101:42 (6th ed.)

Jury Instruction 32. Credibility of Witnesses

In deciding the facts, you may have to decide what testimony to believe and what testimony not to believe. You may believe everything a witness says, part of it, or none of it. In considering the testimony of any witness, you may take into account many factors, including the witness' opportunity and ability to see or hear or know the things the witness testified about; the quality of the witness' memory; the witness' appearance and manner while testifying; the witness' interest in the outcome of the case; any bias or prejudice the witness may have; other evidence that may have contradicted the witness' testimony; and the reasonableness of the witness' testimony in light of all the evidence.

3 FED. JURY PRAC. & INSTR. § 101:43 (6th ed.) (modified)

Jury Instruction 33. Discrepancies in Testimony

You are the sole judges of the credibility of the witnesses and the weight their testimony deserves. You may be guided by the appearance and conduct of a witness, or by the manner in which a witness testifies, or by the character of the testimony given, or by evidence contrary to the testimony.

You should carefully examine all the testimony, the circumstances under which each witness has testified, and every matter in evidence tending to show whether a witness is worthy of belief. Consider each witness' intelligence, motive and state of mind, and demeanor or manner while testifying.

Consider the witness' ability to observe the matters as to which the witness has testified, and whether the witness impresses you as having an accurate recollection of these matters. Also, consider any relation each witness may have with either side of the case, the manner in which each witness might be affected by the verdict, and the extent to which the testimony of each witness is either supported or contradicted by other evidence in the case.

Inconsistencies or discrepancies in the testimony of a witness, or between the testimony of different witnesses may or may not cause you to discredit such testimony. Two or more persons seeing an event may see or hear it differently.

In weighing the effect of a discrepancy, always consider whether it pertains to a matter of importance or an unimportant detail, and whether the discrepancy results from innocent error or intentional falsehood.

After making your own judgment, you will give the testimony of each witness such weight, if any, that you may think it deserves. In short, you may accept or reject the testimony of any witness, in whole or in part.

In addition, the weight of the evidence is not necessarily determined by the number of witnesses testifying to the existence or nonexistence of any fact. You may find that the testimony of one or a small number of witnesses as to any fact is more credible than the testimony of a larger number of witnesses to the contrary.

3 FED. JURY PRAC. & INSTR. § 105:01 (6th ed.) (modified)

Jury Instruction 34. Expert Testimony[112]

Certain testimony was given in this case by experts. An expert is someone who is specially qualified by experience or training and possesses knowledge on matters not common to jurors in general. In a trial, an expert is permitted to give his or her opinions regarding such matters. The testimony of experts is to be considered like any other testimony, is to be tried by the same tests, and should receive such weight and credit as you deem it entitled to, when viewed in connection with all the other facts and circumstances. Its weight and value are questions for you.

[112] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction B-13.

Jury Instruction 35. Publicity—Final Charge

Your verdict must be based solely on the evidence presented in this courtroom in accordance with the instructions. You must completely disregard any report which you have read in the press or on the internet or on social media, seen on television, or heard on the radio. It would be unfair to consider such reports, since they are not evidence and the parties have no opportunity of contradicting their accuracy or otherwise explaining them away. In short, it would be a violation of your oath as jurors to allow yourselves to be influenced in any manner by such publicity.

4 L. SAND, MODERN FEDERAL JURY INSTRUCTIONS (2017), Instr. 71-14 (modified)

Jury Instruction 36. Stipulations of Fact

The parties have stipulated, or agreed, that certain things are facts in this case. You must treat them as having been proven for the purpose of this case.

3 FED. JURY PRAC. & INSTR. § 102:11 (6th ed.)

Jury Instruction 37. Interrogatories

You have heard and seen evidence in this case in the form of interrogatories.

Interrogatories are written questions posed by one side which call for written answers under oath from the other side. The questions and answers are made before trial after the case has begun in what is called pretrial discovery, and each side is entitled to seek such discovery from the other.

You may consider a party's answer to interrogatories as evidence against a party who made the answer, just as you would any other evidence in this case.

You are not required to consider a party's answers to interrogatories as true, nor are you required to give them more weight than any other evidence. It is up to you to determine what weight, if any, should be given to the interrogatory answers which have been admitted as evidence.

One cautionary word on this subject: while you may consider the interrogatory answers as evidence against the party who gave the answers, you may not consider the answers against any other party, nor may you consider the answers as evidence against the party who posed the interrogatory questions. You may only consider the interrogatory answer as evidence against the party who gave the answer.

4 L. SAND, MODERN FEDERAL JURY INSTRUCTIONS (2017), Instr. 74-13

Jury Instruction 38. Charts and Summaries and Graphics [Not Received in Evidence]

Charts and summaries and graphics, generally called "demonstratives," have been shown to you in order to help explain evidence or testimony. These demonstratives, if not admitted into evidence, are not themselves evidence. If the demonstrative does not correctly reflect facts or figures shown by the evidence in the case, you should disregard them. They are used only as a matter of convenience to help you understand the evidence.

3 FED. JURY PRAC. & INSTR. § 104:50 (6th ed.) (modified)

Jury Instruction 40. Summaries and Charts Admitted as Evidence

The Plaintiffs and Defendants have presented certain charts and summaries that were admitted into evidence. I admitted these charts and summaries in order to save time and avoid the burden and inconvenience of presenting a lot of data or documents in court. You should consider these charts and summaries as you would any other evidence.

4 L. SAND, MODERN FEDERAL JURY INSTRUCTIONS (2017), Instr. 74-11 (modified)

Jury Instruction 41. Evidence in Electronic Format

Exhibits received in evidence that can be displayed electronically will be provided to you in that form. You will be able to view those exhibits in the jury room. A computer, projector, printer and other equipment will be available to you.

A court technician will show you how to operate the computer and other equipment, how to locate and view the exhibits on the computer, and how to print the exhibits. You will be provided with a paper list of all exhibits received in evidence. You may request a paper copy of any exhibit received in evidence by sending a note through the clerk. If you need additional equipment or supplies or if you have questions about how to operate the computer or other equipment, you may send a note to the clerk. Do not tell anyone outside the jury which exhibit you were attempting to view.

If a technical problem or question requires hands-on maintenance or instruction, a court technician may enter the jury room with the clerk present for the sole purpose of assuring that the only matter that is discussed is the technical problem. When the court technician or any non-juror is in the jury room, the jury must not deliberate or discuss the case. No juror may say anything to the court technician or any non-juror other than to describe the technical problem or to seek information about operation of the equipment. Do not discuss any exhibit or any aspect of the case in front of non-jurors.

The purpose of providing the computer in the jury room is to enable jurors to view the exhibits received in evidence in this case. You may not use the computer for any other purpose. Technicians have taken steps to ensure that the computer does not permit access to the Internet or to any "outside" website, database, directory, game, or other material. Do not attempt to alter the computer to obtain access to such materials. If you discover that the computer provides or allows

access to such outside materials, you must inform the court immediately and refrain from viewing such materials. Do not remove the computer or any electronic data from the jury room, and do not transmit or copy any such data.

3 FED. JURY PRAC. & INSTR. § 104:55 (6th ed.) (modified)

Jury Instruction 42. Corporate Parties

In this case, the Plaintiffs and Defendants are corporations. The mere fact that the parties are corporations does not mean they are entitled to any lesser consideration by you. All litigants are equal before the law, and corporations, big or small, are entitled to the same fair consideration as you would give any other individual party.

4 L. SAND, MODERN FEDERAL JURY INSTRUCTIONS (2017), Instr. 72-1

Jury Instruction 43. Consideration of the Evidence—Corporate Party's Agents and Employees

A corporation may act only through people who are its agents or employees. Generally, any agents or employees of a corporation may bind the corporation by their acts and declarations made while acting within the scope of their authority delegated to them by the corporation or within the scope of their duties as employees of the corporation. You heard testimony of individuals who, at the time they testified, whether live or by deposition, were former employees. They can still bind their former employer by their acts and declarations made within the scope of their authority delegated to them by the corporation while they were still employees.

3 FED. JURY PRAC. & INSTR. § 103:31 (6th ed.)

B. Plaintiffs' Claims

1. Sherman Act Section 1: Unreasonable Restraints of Trade – Reverse Payment Claims

Jury Instruction 44. Purpose of the Sherman Act

As I told you at the start of trial, Plaintiffs allege that Defendants violated the antitrust laws, specifically a law called the Sherman Act. The purpose of the Sherman Act is to preserve free and unfettered competition in the marketplace. The Sherman Act rests on the central premise that competition produces the best allocation of our economic resources, the lowest prices, the highest quality, and the greatest material progress.[113]

[113] ABA MODEL INSTRUCTIONS, Ch. 1, Instruction A-1.

Jury Instruction 45. Elements of a Conspiracy to Restrain Trade

Plaintiffs here claim that Defendants violated the Sherman Act in two ways, and have two theories of liability. First, Plaintiffs allege that Defendants entered into an agreement that unreasonably restrained trade. Second, Defendants engaged in a hard switch product hop which a court has already found violated the Sherman Act.

As to the first theory, Section 1 of the Sherman Act prohibits contracts, combinations, and conspiracies that unreasonably restrain trade. To establish a violation of Section 1 of the Sherman Act, Plaintiffs must prove the following:

(1) First, the existence of a contract, combination, or conspiracy between or among at least two separate entities;

(2) Second, that the contract, combination, or conspiracy unreasonably restrains trade; and

(3) Third, that the restraint affects interstate or foreign commerce.[114]

As I will explain to you, the first and third elements are not in dispute and therefore you do not need to make any finding with respect to them. You only have to decide the second element,

[114] ABA MODEL INSTRUCTIONS, Ch. 1, Instruction B-2; *Bilinski v. Keith Haring Foundation*, 96 F. Supp. 3d 35, 43 (S.D.N.Y. 2015) ("In order to state a claim under Section 1, a plaintiff must allege (1) a contract, combination or conspiracy between two legally distinct entities, (2) in restraint of trade, (3) affecting interstate commerce.") (citing *E & L Consulting Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2d Cir. 2006) and *Maric v. Saint Agnes Hosp. Corp*., 65 F.3d 310, 313 (2d Cir. 1995)); *Oreck Corp. v. Whirlpool Corp*., 639 F.2d 75, 78 (2d Cir. 1980) (plaintiff "must establish two elements: first, that the defendants entered into a 'contract, combination… or conspiracy'; and second, that it was 'in restraint of trade or commerce among the several states.'") (citing 15 U.S.C. § 1 (1976)); *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 574 n. 5 (S.D.N.Y. 2011) ("To prove a conspiracy (or contract) in restraint of trade in violation of Section 1 of the Sherman Act, a plaintiff must prove two elements: '(1) a combination or some form of concerted action between at least two legally distinct economic entities that (2) unreasonably restrains trade.'") (citing *Freeland v. AT&T Corp.*, 238 F.R.D. 130. 153 (S.D.N.Y. 2006) (quoting *Geneva Pharm. Tech. Corp. v. Barr Lab., Inc.*, 386 F.3d 485, 506 (2d Cir. 2004)).

whether the agreement being challenged unreasonably restrained trade. I will describe each element in more detail.

Jury Instruction 46. Conspiracy to Restrain Trade: Element 1: Existence of a Contract, Combination, or Conspiracy

It is not disputed that Defendants entered into agreements with Mylan on July 21, 2010. These agreements signed by Defendants and Mylan satisfy the "contract, combination, or conspiracy" element. Therefore, this element is not in dispute.[115]

[115] *See* 15 U.S.C. § 1 ("*every contract*… in restraint of trade… is declared to be illegal.") (emphasis added); *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-CV-955-TWT, 2018 WL 2984873, at *8 (N.D. Ga. June 14, 2018) (settlement agreements were "clear, direct evidence of an agreement" and "it is doubtful that a reasonable jury could find otherwise."); *Procaps S.A. v. Pantheon, Inc.*, 845 F.3d 1072, 1080 (11th Cir. 2016) ("Courts use the words 'contract,' 'combination,' and 'conspiracy' interchangeably," as all three reflect the common element… of concerted action.") (internal citations and quotation marks omitted); *In re Lidoderm Antitrust Litigation*, 296 F.Supp.3d 1142, 1166 (N.D. Cal. Nov. 3, 2017) ("*Lidoderm SJ Order*") (in reverse payment case, court concluded that "the Settlement Agreement, signed by all [] defendants satisfies the 'contract, combination, or conspiracy element[]" and defendants did not even dispute the issue); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 410 n. 9 (E.D. Pa. 2015) ("Plaintiffs have presented direct evidence of concerted action through the settlement agreements between Cephalon and each of the Generic Defendants."); *Helicopter Support Sys., Inc. v. Hughes Helicopter, Inc.*, 818 F.2d 1530, 1536 (11th Cir. 1987) ("documentary evidence" such as a written agreement addressing prices, is "direct evidence of an agreement); *Paladin Assoc., Inc. v. Montana Power Co.*, 328 F.3d 1145, 1152-54 (9th Cir. 2003) ("several contracts" between two companies, which "assign[ed] certain contract rights" and were "signed by representatives" of defendants, are "direct evidence of concerted activity."); *Eli Lilly & Co. v. Zenith Goldline Pharm. Inc.*, 172 F. Supp. 2d 1060, 1065, 1073 (S.D. Ind. 2010) (agreement between API supplier and drug manufacturer for former to "not supply [API] to any third party" was "direct evidence of conspiracy"); 6 Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶1400c (4th ed. 2017) ("An undisputed contract remains an agreement for antitrust purposes."); *id.* ¶1416 ("[T]he express contract is the clearest form of conspiracy."). Cf. *Am. Needle, Inc v. Nat'l Football League*, 560 U.S. 183, 186 (2010) (whether the parties engaged in concerted action is "different from and antecedent to the question of whether [that concerted action] unreasonably restrains trade.").

Jury Instruction 47. Conspiracy to Restrain Trade: Element 2: The Rule of Reason and Unreasonable Restraints of Trade

The parties dispute whether the restraint challenged here—the reverse payments and Mylan's promise to delay the entry of generic Namenda IR until at least 2015—is unreasonable.[116] That dispute is for you to decide. Under Section 1 of the Sherman Act, a restraint of trade is illegal only if it is found to be unreasonable.[117]

You must assess whether the agreement here was unreasonable under what is known as the "rule of reason."[118] In making this determination here, you must first determine whether Plaintiffs have proven that Defendants' payments to Mylan and Mylan's promise to delay selling its generic Namenda IR resulted in harm to competition.[119] If you find that Plaintiffs have shown harm to competition, then the burden shifts to Defendants to prove that the payments were justified by legitimate procompetitive benefits.[120] If Defendants prove such legitimate procompetitive

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[116] *Ohio v. American Express*, 138 S. Ct. 2274, 2284 (2018) ("*Amex*") (plaintiff must prove "the *challenged restraint* has a substantial anticompetitive effect") (emphasis added); *In re Impax Labs.*, -- F.T.C. --, No. 9373, 2019 FTC LEXIS 25, at *44-46 (F.T.C. 2019) ("*Impax*") (same).

[117] *Ark. Carpenters Health and Welfare Fund v. Bayer AG*, 604 F.3d 98, 104 (2d Cir. 2010) ("Although by its terms the [Sherman] Act prohibits 'every' restraint of trade, the Supreme Court 'has long recognized that Congress intended to outlaw only unreasonable restraints.'") (citing *State Oil Co., v Khan*, 522 U.S. 3, 10 (1997), *rev'd on other grounds*, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

[118] *Actavis*, 570 U.S. at 152-59.

[119] ABA MODEL INSTRUCTIONS, Ch. 1, Instruction C.1-3A. *See also Namenda V*, 331 F. Supp. 3d at 197 ("First, the plaintiff bears the initial burden of showing that the defendant's conduct 'had an actual adverse effect on competition as a whole in the relevant market."') (quoting *Ark. Carpenters*, 604 F.3d at 104); *Laumann v. National Hockey League*, 56 F. Supp. 3d 280, 291 (S.D.N.Y. 2014) ("In applying the rule of reason, the Second Circuit employs a balance-shifting framework…. [P]laintiffs bear an initial burden to demonstrate the defendants' challenged behavior had an *actual* adverse effect on competition as a whole in the relevant market") (citing *Major League Baseball Prop., Inc. v. Salvino, Inc.*, 542 F.3d 290, 317 (2d Cir. 2008) (emphasis in original).

[120] *See Actavis*, 570 U.S. at 156 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and

benefits, you must then balance the competitive harm against the procompetitive benefit.[121] The reverse payments and Mylan's promise to delay selling generic Namenda IR are illegal under Section 1 of the Sherman Act only if you find that the competitive harm substantially outweighs any legitimate procompetitive benefit.

You have the verdict form in front of you. This is the form you will fill out in rendering your verdict. The first question on the verdict form is: "Did Defendants enter into a reverse

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showing the lawfulness of that term under the rule of reason."); *Namenda V*, 331 F. Supp. 3d at 197 ("If plaintiffs satisfies this burden [of showing actual adverse effect on competition], then the burden then shifts to defendant to offer evidence that is conduct has pro-competitive effects.") (quoting *Ark. Carpenters*, 604 F.3d at 104, *rev'd on other grounds*, *Actavis*, 570 U.S. 136); *Lipitor*, 868 F.3d at 256-57 ("The Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on antitrust defendants."); *Namenda II*, 787 F.3d at 652 ("once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer 'nonpretextual' procompetitive justifications for its conduct.") (quoting *United States v. Microsoft Corp.*, 346 U.S. App. D.C. 330, 253 F.3d 34, 58-59 (2001)); *see also NCAA v. Bd. of Reg. of Univ. of Okla.*, 468 U.S. 85, 113 (1984) (defendants bear "a heavy burden of establishing an affirmative defense which competitively justifies this apparent deviation from the operations of a free market"); *Virgin Atl. Airways v. British Airways PLC*, 257 F.3d 256, 264 (2d Cir. 2001) (once an adverse effect on competition is shown, "burden shifts to [defendants] to establish the procompetitive value of its[] agreements"); *O'Bannon v. Nat'l. Collegiate Athletic Ass'n*, 802 F.3d 1049, 1070 (9th Cir. 2015) ("If the plaintiff meets [its initial burden to show anticompetitive effects], the defendant must come forward with evidence of the restraint's procompetitive effects."); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416, 419-20 (E.D. Pa. 2015) (finding that "the defendant bear[s] the burden of providing evidence that the reverse payment is justified by procompetitive considerations *** Defendants, not Plaintiffs, bear the burden of explaining the payments… [E]vidence that these payments exceed fair value for goods and services…are not a necessary element of plaintiffs' claims."); *Apotex* Final Jury Instructions at 13 ("If Plaintiffs establish adequate evidence of anticompetitive effects or market power, the burden shifts to [defendant] to prove that the challenged conduct promotes sufficiently procompetitive benefits."); *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 263-64 (D. Mass 2014) ("Nowhere in *Actavis* does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny. Neither does the opinion place the initial burden on the Plaintiffs to prove, in their prima facie case, that a transaction was for something other than fair market value.").

[121] ABA MODEL INSTRUCTIONS, Ch. 1, Instruction C.1-3A. *See also United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003) ("The principal question in a rule of reason case is often whether the anticompetitive effects of a restraint are outweighed by some procompetitive justification.").

payment agreement with Mylan that unreasonably restrained trade?" To answer this question, you must decide whether Plaintiffs have proven by a preponderance of the evidence that the reverse payments and Mylan's promise to delay selling generic Namenda IR until January or July 2015, on balance, unreasonably restrained trade.

Jury Instruction 48. Conspiracy to Restrain Trade: Plaintiffs' Burden: Showing Anticompetitive Harm

As I mentioned, to prove that the reverse payments and Mylan's promise to delay selling generic Namenda IR are unreasonable, Plaintiffs first must demonstrate that they resulted in a harm to competition.

A harmful effect on competition, or competitive harm, refers to a reduction in competition that results in the loss of some of the benefits of competition, such as lower prices, increased output, higher product quality, or increased consumer choice.[122] If the challenged conduct has not resulted in the loss of some competitive benefit, then there has been no competitive harm, and you should find that the challenged conduct was not unreasonable.

In determining whether the reverse payments and Mylan's promise to delay selling generic Namenda has produced competitive harm, you should consider that the relevant market here is memantine hydrochloride, and no other products. I instruct you that prior to the entry of generic versions of Namenda IR in the U.S. market in July 2015, Defendants held a monopoly over memantine hydrochloride.[123] A monopoly means that Defendants had the ability to control prices or exclude competition.[124] That also means that if Defendants' payment to Mylan delayed when generic competition would have begun, then Defendants' payment to Mylan allowed the Defendants to maintain their monopoly over memantine hydrochloride. In other words, Defendants

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[122] ABA MODEL INSTRUCTIONS, Ch. 1, Instruction C-3B.

[123] *Namenda IV*, 2017 WL 4358244, at *10, 16 (adopting Judge Sweet's conclusion on relevant market and concluding that "mean[s] that Forest [has] monopoly power" and therefore "Forest is precluded from relitigating the question[] of (1) whether it possessed monopoly power over the U.S. memantine market up until the entry of generic competition[.]") (internal quotes and citation omitted).

[124] *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956) (monopoly power is "the ability to control prices or exclude competition").

were the sole competitor in the relevant market both before and after the restraint was imposed, and until Mylan and others entered the market with generics in July 2015.

You may also consider the purpose and nature of the payments Defendants made to Mylan and the effect of the payments on the prices of Namenda IR and the ability of purchasers to buy generic versions of Namenda IR at prices below branded Namenda IR or XR.

Jury Instruction 49. Conspiracy to Restrain Trade: Plaintiffs' Burden: Showing Anticompetitive Harm: Reverse Payments

In assessing the competitive effects of a reverse payment, you should consider that "genuine adverse effects on competition" arise when a settlement includes "payment[s] in return for staying out of the market" or payment "to prevent the risk of competition" or payment to "avoid the risk of patent invalidation or a finding of noninfringement."[125] "Reverse payments are of particular concern when they demonstrate that the patentee [sought] to induce the … [infringer] to abandon its claim."[126] Here, Defendants were the "patentee" and Mylan was the alleged infringer.

If you find that Defendants' reverse payments to Mylan had the purposes and effects I have discussed, then Plaintiffs have met their burden to show harm to competition.

[125] *Actavis*, 570 U.S. at 153, 156, 157. *See also Impax*, 2019 FTC LEXIS 25, at *67 ("the harm *Actavis* recognizes is the elimination of *the risk of* competition, not proof that entry would actually or probably have occurred earlier.") (emphasis in original).

[126] *Namenda V*, 331 F. Supp. 3d at 197 (alterations in original).

Jury Instruction 50. Conspiracy to Restrain Trade: Size of Reverse Payment

In assessing the anticompetitive effects of a reverse payment, one important factor is whether the reverse payment that you find Defendants made is "large." To cause anticompetitive harm that is illegal under the Sherman Act, reverse payments must be large. You should consider the various components of the payments that Defendants conferred on Mylan in the Lexapro Amendment together, not separately, in making this determination.[127]

Here is a guide that will help you determine whether the reverse payments are large. From the standpoint of the parties making the payments, you can find the reverse payments here were large if they are larger than the additional legal fees and expenses that Defendants would have paid to their patent lawyers to continue the patent case against Mylan after the time of the settlement, assuming they had not settled.[128] From the standpoint of the party receiving the payments, you can find the reverse payments to be large if they were large enough to induce or persuade Mylan to abandon its patent challenge and agree not to compete with Defendants.[129] A reverse payment

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[127] *Namenda V*, 331 F. Supp. 3d at 198 n.6 (analyzing "whether the deal, taken as a whole, constituted an unlawful reverse payment.").

[128] *Actavis*, 570 U.S. at 156. *See also Namenda V*, 331 F. Supp. 3d at 174 (analyzing whether "payment exceeded avoided litigation costs… is fully consistent with *Actavis*."); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-CV-6549 (CM), 2016 WL 4992690, at *14 (S.D.N.Y. Sept. 13, 2016) ("*Namenda III*") (*Actavis* instructed "compar[ing] a payment to the payor's future litigation costs as a measure of scale to determine if it was 'large[]'"); *Opana*, 162 F. Supp. 3d at 718 ("A 'large' payment is anything more than the value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer."); *Apotex* Final Jury Instructions at 15 ("you must ask whether the payment exceeds the patent holder's – here, Cephalon's – anticipated future litigation costs.").

[129] *Actavis*, 570 U.S. at 154 (describing the anticompetitive consequences of a reverse payment as "induc[ing] the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market"). In describing the features of an anticompetitive reverse payment agreement, the Supreme Court explained that "patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market." *Id.* *See also Namenda V*, 331 F. Supp. 3d at 197 ("Reverse payments are of particular concern when they demonstrate that the

that comes close to or exceeds the profits that Mylan expected to earn if it won the patent litigation may be found to be large enough to have induced Mylan to drop its patent challenge.[130]

A "payment" can be anything or a combination of things of value given to Mylan from Defendants.[131]

Here, Plaintiffs contend that, in total, reverse payments in the form of the benefits conferred to Mylan by the Lexapro Amendment are worth tens of millions of dollars, and that the legal fees and expenses that Defendants would have paid to their patent lawyers to continue the patent case against Mylan after the time of the settlement were at most $3.5 million. Defendants dispute this.

Plaintiffs also contend that the payments given to Mylan by Forest were more than Mylan could have earned by winning the Namenda patent suit and launching a generic version of Namenda. Defendants dispute this.

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patentee [sought] to induce the … [infringer] to abandon its claim.") (alterations in original); *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-CV-955-TWT, 2018 WL 2984873, at *11 (N.D. Ga. June 14, 2018) ("The size of the payment is merely the Supreme Court's proxy for reaching the ultimate question: whether the agreement was entered into for the purpose of avoiding the risk of competition. If a settlement was agreed to for that purpose, it is 'large and unjustified.'"); *Apotex* Final Jury Instructions at 15 (instructing jury to "consider whether the payment was significant enough to induce a generic challenger – here, Ranbaxy – to abandon its patent claim and stay off the market.").

[130] *Namenda V*, 331 F. Supp. 3d at 199.

[131] *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-CV-6549 (CM), 2016 WL 4992690, at *15 (S.D.N.Y. Sept. 13, 2016) (noting the early entry provisions here may be anticompetitive); *Lidoderm MTD Order*, 74 F. Supp. 3d at 1070 ("I agree with the bulk of the recent decisions holding that courts need not restrict the definition of 'payments' under *Actavis* to cash.") (collecting cases); *Lipitor*, 868 F.3d at 252 ("a reverse payment underlying an *Actavis* antitrust claim need not be in cash form") (citing *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015) ("*Lamictal*"); *In re Loestrin 24 FE Antitrust Litig.*, 814 F.3d 538, 550-51 (1st Cir. 2016) ("[T]he key word used throughout [*Actavis*] is "payment," which connotes a much broader category of consideration than cash alone.") (collecting cases); *King Drug*, 791 F.3d at 403 ("We do not believe *Actavis* 's holding can be limited to reverse payments of cash.").

Jury Instruction 51. Conspiracy to Restrain Trade: Defendants' Burden: Procompetitive Benefits of Reverse Payment

If you find that Plaintiffs have proven that the reverse payments resulted in harm to competition, then you next must determine whether the reverse payments and Mylan's promise to delay selling generic Namenda IR until January or July 2015 benefitted competition in other ways or are otherwise justified.[132] The burden is on the Defendants to prove that the reverse payments and Mylan's promise not to sell generic Namenda IR until January or July 2015 had procompetitive effects or were otherwise justified.[133] If you find that the reverse payments and Mylan's promise to delay entry until January or July 2015 substantially harmed competition, and did not have

[132] ABA MODEL INSTRUCTIONS, Ch. 1, Instruction C-3C.

[133] *See Actavis*, 570 U.S. at 156 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."); *Lipitor*, 868 F.3d at 256-57 ("The Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on antitrust defendants."); *see also Amex*, 138 S. Ct. at 2284 ("the burden shifts to [defendant] to show a procompetitive rationale for the restraint"); *NCAA*, 468 U.S. at 113 (defendants bear "a heavy burden of establishing an affirmative defense which competitively justifies this apparent deviation from the operations of a free market"); *Ark. Carpenters*, 604 F.3d at 104 (once plaintiffs have established that defendants' conduct had an actual adverse effect on competition, "the burden then shifts to defendants to offer evidence that its conduct had procompetitive effects."), *rev'd on other grounds, Actavis*, 570 U.S. 136; *Virgin Atl. Airways*, 257 F.3d at 264 (once an adverse effect on competition is shown, "burden shifts to [defendants] to establish the procompetitive value of its[] agreements"); *Lipitor*, 868 F.3d at 256-57 ("The Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on antitrust defendants."); *O'Bannon*, 802 F.3d at 1070 ("If the plaintiff meets [its initial burden to show anticompetitive effects], the defendant must come forward with evidence of the restraint's procompetitive effects."); *King Drug*, 88 F. Supp. 3d at 416, 419-20 (finding that "the defendant bear[s] the burden of providing evidence that the reverse payment is justified by procompetitive considerations *** Defendants, not Plaintiffs, bear the burden of explaining the payments… [E]vidence that these payments exceed fair value for goods and services…are not a necessary element of plaintiffs' claims."); *Apotex* Final Jury Instructions at 13 ("If Plaintiffs establish adequate evidence of anticompetitive effects or market power, the burden shifts to [defendant] to prove that the challenged conduct promotes sufficiently procompetitive benefits."); *Nexium*, 42 F. Supp. 3d at 263-64 ("Nowhere in *Actavis* does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny. Neither does the opinion place the initial burden on the Plaintiffs to prove, in their prima facie case, that a transaction was for something other than fair market value.").

procompetitive benefits or were not justified, then you must find that they were unreasonable and answer "Yes" to question No. 1 on the verdict form. Unless Defendants prove some other explanation for the reverse payments to Mylan, what Defendants received in return for the reverse payments is likely an anticompetitive promise by Mylan to delay the introduction of generic Namenda IR, which I am instructing you is unreasonable.[134]

Not all reasons for reverse payments are properly considered to be procompetitive justifications under the rule of reason.[135] For a claimed explanation to justify the payments and Mylan's promise to delay competing, the explanation must show that Defendants' conduct had procompetitive benefits in the relevant market (here, the memantine hydrochloride market).[136]

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[134] *Actavis*, 570 U.S. at 157 (holding that an "unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival" which "in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market--the very anticompetitive consequence that underlies the claim of antitrust unlawfulness").

[135] *Lidoderm SJ Order*, 296 F. Supp. 3d at 1183 ("justification[s] [for reverse payment] must be *relevant* to the 'rule of reason' analysis.") (citing *Actavis*, 570 U.S. at 156-57)).

[136] ABA MODEL INSTRUCTIONS, Ch. 1, Instruction C-3C, Note ("Benefits that are unrelated to competition should be irrelevant to the analysis"). Asserted procompetitive benefits must be the relevant market. *United States v. Topco Assocs.*, 405 U.S. 596, 610 (1972) ("[Competition] cannot be foreclosed with respect to one sector of the economy because certain private citizens or groups believe that such foreclosure might promote greater competition in a more important sector of the economy."); *Lamictal*, 791 F.3d at 410 n.34 (noting that it may be that "procompetitive effects in one market cannot justify anticompetitive effects in a separate market," although declining to decide the issue) (internal quotes omitted); *Sullivan v. NFL*, 34 F.3d 1091, 1112 (1st Cir. 1994) ("it seems improper to validate a practice that is decidedly in restraint of trade simply because the practice produces some unrelated benefits to competition in another market"); *Law v. NCAA*, 902 F. Supp. 1394, 1406 (D. Kan. 1995) ("Procompetitive justifications for price-fixing must apply to the same market in which the restraint is found, not to some other market."), *aff'd*, 134 F.3d 1010 (10th Cir. 1998); *L.A. Mem'l Coliseum Comm'n v. NFL*, 726 F.2d 1381, 1392 (9th Cir. 1984) ("[T]he relevant market provides the basis on which to balance competitive harms and benefits of the restraint at issue."). *See also Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 688 (1978) (The rule of reason "does not open the field of antitrust inquiry to any argument in favor of a challenged restraint," but instead "focuses directly on the challenged restraint's impact on competitive conditions."); *NCAA*, 468 U.S. at 1114 ("If the NCAA's television plan produced procompetitive efficiencies, the plan would increase output and reduce the price of televised

Benefits that are unrelated to competition in the memantine hydrochloride market are irrelevant and you are instructed not to consider them.

Nor should you consider claimed justifications that are pretextual, which means a justification which is false or not the real reason. You should not consider a justification that is speculative, and you should not consider a justification that is not related to the reverse payments.[137] Because the relevant restraint alleged here is "the payment in exchange for the elimination of the risk of [generic] entry[,]" Defendants must show that procompetitive benefits

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games."); *In re NCAA Student-Athlete Name & Likeness Licensing Litig.*, 37 F. Supp. 3d 1126, 1149 (N.D. Cal. 2014) (denying defendants' motion for summary judgment where defendants "have not cited any evidence to suggest that the NCAA's restrictions on student-athlete compensation—the specific restraint challenged in this case—*actually help* the NCAA achieve that level of competitive balance.") (emphasis added); *id.* at 1151 ("Thus, if the NCAA seeks to argue at trial that the challenged restraint promotes the integration of education and athletics, it must present evidence to show that (1) the ban on student-athlete compensation *actually contributes* to the integration of education and athletics and (2) the integration of education and athletics enhances competition in the 'college education' or 'group licensing' market.") (emphasis added); *Lidoderm SJ Order*, 296 F. Supp. 3d at 1184 (finding that Teikoku's 'good business relationship' defense was not cognizable because "Teikoku does not show how that goal has any pro-competitive impact on consumer or the industry in general, or on any other consideration relevant to a rule of reason analysis").

[137] *Namenda II*, 787 F.3d at 658 ("Because we have determined that Defendants' procompetitive justifications are pretextual, we need not weigh them against the anticompetitive harms."); *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695-96 (1978) (rejecting justification as not cognizable); *Cal. v. Safeway, Inc.*, 651 F.3d 1118, 1160 (9th Cir. 2011) (asserted procompetitive benefits were "purely speculative"); *In re NCAA Student-Athlete Name & Likeness Licensing Litig.*, 37 F. Supp. 3d 1126, 1151 (N.D. Cal. 2014) (to be admissible, defendants had to produce evidence that restraint actually yielded benefit and that benefit actually enhanced competition); *Realcomp II, Ltd. v. F.T.C.*, 635 F.3d 815, 835 (6th Cir. 2011) (defendant "has not demonstrated a connection between the website policy of [prohibiting certain listings from being publicly distributed] and the prevention of free-riding"); *N. Tex. Specialty Physicians v. F.T.C.*, 528 F.3d 346, 369 (5th Cir. 2008) (defendant had "no theory as to how its proffered procompetitive effects, which we will assume are higher quality healthcare provided by teamwork and shared experiences over time, result from or are in any way connected to" the challenged minimum pricing restrictions); *Law*, 134 F.3d at 1024 (restraint and proffered procompetitive justification were not sufficiently connected).

were tied to the elimination of this risk.[138] Defendants cannot justify a reverse payment by arguing that it was made to "prevent the risk of competition" or because the Defendants was "risk averse" because the avoidance of the risk of competition constitutes anticompetitive harm, not a justification.[139] Nor can Defendants cannot try to justify the payments by pointing to justifications for the agreements as a whole.[140]

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[138] *Actavis*, 570 U.S. at 158 ("[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; *one who makes such a payment may be unable to explain and to justify it*.") (emphasis added); *Impax*, 2019 FTC LEXIS 25, at *98 (citing *Actavis*, 570 U.S. at 157). *See also Lipitor*, 868 F.3d at 256 (defendants have the burden of justifying the rather large reverse payment here, and they offer no reason why those other elements of the settlement agreement do so"); *In re Cipro Cases I & II*, 348 P.3d 845, 865 (Cal. 2015) (describing restraint in reverse payment as the "limit on the settling generic challenger's entry into the market" in exchange for "cash or equivalent financial consideration flowing from the brand to the generic challenger."); *id*. at 871 ("That payment for delay is condemned . . . by federal antitrust law, and its purchase as part of a settlement agreement is an unlawful restraint of trade."); *In re Aggrenox Antitrust Litig*., 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (noting that defendants might be able to "explain the apparent 'missing' value for the patent-holder in a procompetitive way . . . in which case the reverse payment may turn out to be justified, or to be entirely illusory").

[139] *Actavis*, 570 U.S. at 156.

[140] *See NCAA*, 468 U.S. at 104 (defendant must show "the challenged restraint enhances competition."); *Amex*, 138 S.Ct. 2284 (plaintiff must prove "the *challenged restraint* has a substantial anticompetitive effect") (emphasis added); *Visa*, 344 F.3d at 238, 243 (explaining that defendants "must provide a procompetitive justification for the challenged restraint," and sustaining district court's finding that "no evidence" showed that the restraint advanced the proffered justifications); *Impax*, 2019 FTC LEXIS 25, at *97 ("to justify a challenged restraint, Impax must 'articulate the specific link between the challenged restraint and the purported justification,' and demonstrate that the restraint in fact 'advance[s] procompetitive goals.'") (quoting *Polygram Holding, Inc.*, 136 F.T.C. 310, 347 (2003), *enforced, Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005). *See also N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 368-69 (5th Cir. 2008) (defendant must show that the restraint bears a "logical nexus to [the] claimed efficiencies," meaning that the efficiencies either "result from or are in any way connected to" the restraint); *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 835 (6th Cir. 2011) (affirming FTC's finding that the respondent had not "demonstrated a connection" between the restraint and the proffered rationale).

Instead, Defendants must show that the alleged restraint – here, a payment to prevent earlier generic entry – itself advanced procompetitive objectives.[141] In conducting this inquiry, you should consider whether Defendants could achieved the asserted procompetitive objectives "without a *reverse payment* for delayed generic entry."[142] If the reason for the payments was to induce, or persuade, Mylan to abandon its patent challenge or to agree to delay launching its generic version of Namenda IR, that is not a pro-competitive reason.[143]

There are other types of explanations for reverse payments that you should not consider:

- If the reason for the reverse payment "is a desire to maintain and to share patent-generated monopoly profits," that is not a procompetitive benefit or justification under the rule of reason.[144]
- It is not a justification for a reverse payment that Defendants had a patent allegedly covering Namenda IR.[145] A brand company that holds a patent is still subject to antitrust laws.[146] A patent does not permit the brand company to pay a generic

[141] *Impax*, 2019 FTC LEXIS 25, at *111.

[142] *Id.* at 112 (emphasis in original).

[143] *Actavis*, 570 U.S. at 156 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.").

[144] *Actavis*, 570 U.S. at 158.

[145] *Actavis*, 570 U.S. at 147 ("to refer, as the Circuit referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent here may or may not be valid, and may or may not be infringed"); *Namenda II*, 787 F.3d at 660 ("The Court's decision in *Actavis* reaffirmed the conclusions of circuit courts that a patent does not confer upon the patent holder an 'absolute and unfettered right to use its intellectual property as it wishes' and '[i]ntellectual property rights to not confer a privilege to violate the antitrust laws.'").

[146] *Actavis*, 570 U.S. at 148 ("it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well").

competitor to stop challenging the patent and agree not to compete.[147] In determining whether the reverse payments were anticompetitive, you are not required to make any findings about the likelihood that either side would have won the patent litigation.[148] It is enough that Defendants could have lost, and Mylan could have won.[149]

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[147] *Actavis*, 570 U.S. at 151 (rejecting the notion that "a patent holder may simply pay a competitor to respect its patent and quit its patent invalidity or noninfringement claim without any antitrust scrutiny") (internal quotations omitted).

[148] *Actavis*, 570 U.S. at 157 ("[I]t is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham). An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness."); *id*. at 147 ("Solvay's patent, if valid and infringed, might have permitted it to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors. And we are willing to take this fact as evidence that the agreement's anticompetitive effects fall within the scope of the exclusionary potential of the patent. But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack.") (internal quotation omitted); *id.* at 147 ("to refer, as the Circuit referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent here may or may not be valid, and may or may not be infringed"); *In re Aggrenox Antitrust Litig.*, 94 F.Supp.3d 224, 241-42 (D. Conn. 2015) ("The salient question is not whether the fully-litigated patent would ultimately be found valid or invalid—that may never be known—but whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition."); *Lamictal*, 791 F.3d at 410 (*Actavis* "embraces" the fact that at the time of settlement a patent "may or may not be valid, and may or may not be infringed"); *Cipro*, 348 P.3d at 870 ("Agreements must be assessed as of the time they are made, at which point the patent's validity is unknown and unknowable.") (internal citation omitted).

[149] *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-CV-955-TWT, 2018 WL 2984873, at *11 (N.D. Ga. June 14, 2018) ("even if the patent was valid and infringed, the Defendants took away the opportunity to know that for sure by settling before the end of the litigation. If they did so for the purpose of avoiding the risk that a court would find otherwise, however small a risk they considered it to be, that is an antitrust violation under *Actavis*."); *Lidoderm SJ Order*, 296 F. Supp. 3d at 1155 (plaintiffs need not prove in that generic would have won its patent litigation: That "is not required (or even suggested) by the *Actavis* opinion.").

- It is not a justification for the reverse payments that the date on which the Settlement and License Agreement authorized Mylan to begin selling generic Namenda (January or July 2015) is earlier than the date on which Defendants' claim their patent rights and/or marketing exclusivity for Namenda IR would have expired.[150] You must instead consider whether the reverse payments that were included in the Settlement and License Agreement in the form of the contemporaneous Lexapro Amendment were made in exchange for Mylan's agreement to delay the launch of its generic version of Namenda.

[150] To instruct otherwise would simply revive the overturned "scope of the patent" standard. *Actavis*, 570 U.S. at 147 (rejecting the argument that one party's ownership of a patent which, "if valid and infringed, might have permitted it to charge" high drug prices because the patent does not "immunize the [alleged reverse payment] agreement from antitrust attack"); *id.* at 147 (A "*valid* patent excludes all except its owner from the use of the protected process or product . . . . But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe.") (citation and internal quotation marks omitted) (emphasis in original); *id.* at 145 ("Under the terms of the settlement Actavis agreed that it would not bring its generic to market until August 31, 2015, 65 months before Solvay's patent expired"). *See also In re Androgel Antitrust Litig. (No. II)*, No. 1:09-CV-955-TWT, 2018 WL 2984873, at *11 (N.D. Ga. June 14, 2018) ("even if the patent was valid and infringed, the Defendants took away the opportunity to know that for sure by settling before the end of the litigation. If they did so for the purpose of avoiding the risk that a court would find otherwise, however small a risk they considered it to be, that is an antitrust violation under *Actavis*.").

- It is not a justification that the reverse payments furthered the business interests of Defendants.[151] Any claimed justification must benefit competition in the memantine hydrochloride market, and not simply Defendants or Mylan.[152]

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[151] *Lidoderm SJ Order*, 296 F. Supp. 3d at 1183-84 ("[P]romotion of self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct. It is only if the conduct is not unlawful in its impact in the market place or if the self-interest coincides with the statutory concern with the preservation and promotion of competition that protection is achieved.") (quoting *Anderson v. Am. Auto. Ass'n*, 454 F.2d 1240, 1246 (9th Cir. 1972); *see also Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 688 (1978) (The rule of reason "does not open the field of antitrust inquiry to any argument in favor of a challenged restraint," but instead "focuses directly on the challenged restraint's impact on competitive conditions."); *Lipitor*, 868 F.3d at 263 ("benign intent does not shield anticompetitive conduct from liability" because "antitrust inquiry is confined to a consideration of impact on competitive conditions") (internal quotation marks and citations omitted); *Levine v. Cent. Florida Med. Affiliates*, 72 F.3d 1538, 1552 (11th Cir. 1996) ("The rule of reason analysis is concerned with the actual or likely effects of defendants' behavior, not with the intent behind that behavior.").

[152] *Namenda V*, 331 F. Supp. 3d at 197 ("the rule of reason analysis focuses on whether defendants' conduct "had an *actual* adverse effect on *competition as a whole* in the relevant market") (emphasis added). *See also United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 375 (1967) ("[t]he promotion of self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct. It is only if the conduct is not unlawful in its impact in the marketplace or if the self-interest coincides with the statutory concern with the preservation and promotion of competition that protection is achieved."), *overruled on other grounds by Cont'l T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977)). *See also United States v. Masonite Corp.*, 316 U.S. 265, 276 (1942) ("the fact that there were business reasons which made the arrangements desirable" was not a justification for a patent settlement that fixed prices). Or as the Court in *Lidoderm* stated, "justifications that benefit only the settling parties and not the market or consumers are not admissible." *In re Lidoderm Antitrust Litig.*, 3:14-md-02521, 2018 WL 7814761, at *2 (N.D. Ca. Feb. 7, 2018). *See also id.* at *6 (procompetitive justifications "that benefit only the settling parties and not the market or consumers" are not considered under Rule of Reason). *See also Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1341 (Fed. Cir. 2006) (explaining that the Supreme Court has found rejected the argument that anticompetitive conduct "should be excused on the ground that it provided benefits and furthered a public policy unrelated to competition"); *LePage's, Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003) (defense that defendant was merely "act[ing] in furtherance of its economic interests does not constitute the type of business justification that is an acceptable defense to §2 monopolization"); *Freeman v. San Diego Ass'n of Realtors*, 322 F.3d 1133, 1152 n.24 (9th Cir. 2003) ("It does not matter that Fallbrook and Valley Center would have operated at a loss in a competitive environment. Their precarious financial situation may have explained their intransigence, but it does not transform it into a viable defense. If there is any argument the Sherman Act indisputably forecloses, it is that price fixing is necessary to save companies from losses they would suffer in a competitive market."); *United Food & Commer. Workers Local 1776*

- It is not a justification that the Defendants' may say they had good intentions.[153]

- Finally, you may not consider any justification that any payment to Mylan was offset because Defendants may have saved money or avoided liability to third parties; what matters is any consideration that could induce Mylan to forfeit its patent challenge. That Defendants could avoid liability to a third party does not offset any inducement that Defendants conferred upon Mylan; only a return of value from Mylan could provide such an offset.[154]

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v. Teikoku Pharma USA, 296 F. Supp. 3d 1142, 1183 (N.D. Cal. 2017) ("While maintaining good business relations with Endo might have been a key goal of Teikoku, Teikoku does not show how that goal has any pro-competitive impact on consumers or on the industry in general, or on any other consideration relevant to a rule of reason analysis. That justification, if true, does nothing to negate the inference (or according to plaintiffs, the actuality) that the payments agreed to by Endo and Teikoku were to delay competition.") (emphasis in original); *Meijer Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 63 n.24 (D.D.C. 2008) ("[a]lthough the Court does not reach the merits of Barr's proffered procompetitive benefits, the Court notes that 'benefits' are only procompetitive when they promote and protect competition, not competitors . . . and when they do not rely on the assumption that competition itself is unreasonable") (citations omitted); ABA MODEL INSTRUCTIONS, Instruction 3C at Notes ("Benefits that are unrelated to competition should be irrelevant to the analysis.") (citing *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 462 (1986) and *Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. 679 (1978)); *see also* Am. Bar Assoc., *Antitrust Law Developments (Eighth)* at 75 (8th ed. 2017) ("Because the rule of reason focuses on anticompetitive effects, factors unrelated to the restraint's effect on competition are generally irrelevant to the analysis.").

[153] *Lidoderm SJ Order*, 296 F. Supp. 3d at 1184 & n.48.

[154] *Namenda V*, 331 F. Supp. 3d at 199 (quoting *King Drug Co. of Florence v. Cephalon*, Inc., 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015). *See also Actavis*, 570 U.S. at 154 (the question is whether "the patentee seeks *to induce the generic challenger to abandon its claim* with a share of its monopoly profits that would otherwise be lost in the competitive market.") (emphasis added); *In re Loestrin 24 Fe Antitrust Litig.*, No. MDL No. 13-2472-S-PAS, 2017 WL 3600938, at *17 (D.R.I. Aug. 8, 2017) ("[t]he [Supreme] Court's use of the word 'induce' suggests that *the value to the alleged infringer is paramount* . . .") (emphasis added). *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (reverse payment is unlawful if "viewed holistically, it effects a large and unexplained *net transfer of value from the patent-holder to the alleged patent-infringer*.") (emphasis added).

Jury Instruction 52. Conspiracy to Restrain Trade: Defendants' Burden: Pretext

As part of their burden to establish a procompetitive justification, Defendants are required to prove that the procompetitive justifications they have offered are the real "nonpretextual" reasons for the restraint.[155] Only if you find that Defendants' procompetitive justifications are nonpretextual are you required to engage in the balancing of anticompetitive harm versus procompetitive benefit described below.[156]

Here, Defendants contend that the payments were not made to induce Mylan to delay, but rather reflected fair value for the additional commitments Mylan agreed to in the Lexapro Amendment. You must assess whether Defendants have proven this is a legitimate, non-pretextual justification for the payment to Mylan.

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[155] *Namenda II*, 787 F.3d at 652 ("once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer 'nonpretextual' procompetitive justifications for its conduct.") (quoting *United States v. Microsoft Corp.*, 346 U.S. App. D.C. 330, 253 F.3d 34, 58-59 (2001)); *id*. at 658 ("All of Defendants' procompetitive justifications for withdrawing IR are pretextual. The record is replete with evidence showing that Defendants were, in the words of Defendants' own CEO, 'trying to . . . put up barriers or obstacles' to generic competition.").

[156] *Id*.

Jury Instruction 53. Conspiracy to Restrain Trade: Least Restrictive Means

If you find that the reverse payments and Mylan's agreement not to sell generic Namenda until January or July 2015 did result in procompetitive benefits in the market for memantine hydrochloride market, then you also must consider whether the reverse payments and Mylan's agreement to delay generic entry were the least restrictive means to achieve those benefits.[157] If Plaintiffs prove that the same benefits could have been achieved by other, reasonably available alternative means that create substantially less harm to competition, then the benefits cannot be used to justify the reverse payments or Mylan's delay in competing with its generic, and you cannot consider them as justifying any harm to competition Plaintiffs have proved.[158] If you find that procompetitive benefits that Defendants assert could have been achieved without the reverse

[157] *See Namenda V*, 331 F. Supp. 3d at 197 ("If defendant is able to offer such proof [of pro-competitive effects], the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives.") (quoting *Ark. Carpenters*, 604 F.3d at 104); *Amex*, 138 S.Ct. 2284 (if procompetitive benefits are proven, burden shifts to plaintiff to show "that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means."); *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs*., Inc., 996 F.2d 537, 543 (2d Cir. 1993) (if defendant establishes procompetitive benefits, "the burden shifts back to plaintiff for it to demonstrate that any legitimate collaborative objectives proffered by defendant could have been achieved by less restrictive alternatives, that is, those that would be less prejudicial to competition as a whole."); *Visa*, 344 F.3d at 238; *Bhan v. NME Hosps., Inc.*, 929 F.2d 1404, 1410 n.4 (9th Cir. 1991) ("are there other and better ways — so-called less restrictive alternatives — by which the collaborators can achieve their legitimate objectives with fewer harms to competition?") (quotation omitted); *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1103 (1st Cir. 1994) ("One basic tenet of the rule of reason is that a given restriction is not reasonable, that is, its benefits cannot outweigh its harm to competition, if a reasonable, less restrictive alternative to the policy exists that would provide the same benefits as the current restraint."); *Kreuzer v. Am. Acad. of Periodontology*, 735 F.2d 1479, 1494–95 (D.C. Cir. 1984) ("[E]ven if evidence existed in the record to support the asserted justification that the limited practice requirement improved the quality of patient care, it must be shown that the means chosen to achieve that end are the least restrictive available."); ABA MODEL INSTRUCTIONS, Ch. 1, Instruction 3C.

[158] ABA MODEL INSTRUCTIONS, Ch. 1, Instruction C-3C; *Tanaka*, 252 F.3d at1063 (same); *Bhan*, 929 F.2d at 1413 (same).

payments and delay, then those other procompetitive benefits cannot justify the reverse payments and delay.

Here, Plaintiffs contend that any competitive benefits from the reverse payments and Mylan's delay could have been achieved without reverse payments and delayed generic competition through a settlement without reverse payments and with an earlier date for generic competition.

Jury Instruction 54. Conspiracy to Restrain Trade: Least Restrictive Means: Brands and Generics Do Not Need to Make or Receive Payments in Order to Settle Patent Case

I instruct you that brand and generic pharmaceutical companies can settle their patent cases without the brand manufacturer paying the generic manufacturer. They can do so, for example, by simply compromising on the date when the generic may enter the market.[159] The idea behind such a lawful settlement, one without reverse payments, is that the brand and generic will bargain with each other over the strengths and weaknesses of the patent suit brought by the brand against the generic. The brand will seek to convince the generic to accept an entry date as late as possible, while the generic will argue the opposite, that the brand's patent is invalid or not infringed or both, and seek to convince the brand to accept an entry as early as possible.[160]

[159] *Actavis*, 570 U.S. at 158. *See also Impax*, 2019 FTC LEXIS 25, at *121-23.

[160] *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014).

Jury Instruction 55. Conspiracy to Restrain Trade: Balancing Competitive Harms and Benefits

If you find that Defendants' procompetitive justifications were not pretextual, and if you find that the reverse payments and Mylan's promise not to sell generic Namenda until January or July 2015 were the least restrictive means of achieving the competitive benefits Defendants have proven, then you must balance the competitive benefits Defendants have proven against the competitive harm that Plaintiffs have proven.

If the competitive harm from the reverse payments and Mylan's delay substantially outweighs the proven, nonpretextual procompetitive benefits, then the challenged restraint is unreasonable and should answer "Yes" to the first question on the verdict form. If the competitive harm does not substantially outweigh those benefits, then the challenged restraint is reasonable and you should answer "No" to the first question on the verdict form.

Although Defendants and Mylan may have reasons why they preferred to settle with reverse payments, the relevant question for you in this trial is: "What are those reasons?" If the basic reason that Defendants and Mylan preferred to settle with large payments was a "desire to maintain and to share patent-generated monopoly profits . . . the antitrust laws are likely to forbid the arrangement."[161] The Supreme Court has held that unless Defendants provide some other explanation, what the brand is getting in return for a reverse payment is likely an agreement by the

[161] *Actavis*, 570 U.S. at 158; *Namenda II*, 787 F.3d at 658 ("All of Defendants' procompetitive justifications for withdrawing IR are pretextual. The record is replete with evidence showing that Defendants were, in the words of Defendants' own CEO, 'trying to . . . put up barriers or obstacles' to generic competition.").

generic to delay the introduction of its generic drug.[162] I instruct you that such an agreement would be anticompetitive.[163]

[162] *Actavis*, 570 U.S. at 157 ("the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm"); *Lipitor*, 868 F.3d at 251 ("On the other hand, in the absence of a legitimate justification or explanation, the reverse payment 'likely seeks to prevent the risk of competition' in that its 'objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market.'") (citations omitted).

[163] *Actavis*, 570 U.S. at 157 (an "unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival" which "in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market — the very anticompetitive consequence that underlies the claim of antitrust unlawfulness").

Jury Instruction 56. Conspiracy to Restrain Trade: Element 3: Effect on Interstate Commerce

Recall that I told you that two of the three elements of Plaintiffs' claim regarding the challenged agreement between Defendants and Mylan are not in dispute. I have discussed the first two elements, one of which is not dispute, and one which is. As to the third element, I instruct you that Defendants' activities affected interstate and/or foreign commerce.[164] You do not, therefore, need to make any findings on this element. I am instructing you that this element of Plaintiffs' case is satisfied.

[164] *See* Forest Defendants' Answer to Direct Purchaser Plaintiffs' First Amended Class Action Complaint, ECF No. 107 (Sept. 27, 2016) ("Forest admits, for the purposes of this litigation, that it made sales in interstate commerce.").

2. Sherman Act Section 2: Monopolization

Jury Instruction 57. Elements of Monopolization

Plaintiffs allege that they were injured by Defendants' unlawful monopolization of the memantine hydrochloride market through Defendants' conversion of the memantine hydrochloride market from Namenda IR to XR by means of an unlawful "hard switch product hop."

Plaintiffs also allege they were injured by Defendants' unlawful monopolization of the memantine hydrochloride market as a result of the reverse payments Defendants made to Mylan to delay Mylan's launch of its generic Namenda IR product.

To prevail on each of these theories, which are brought under Section 2 of the Sherman Act, Plaintiffs must prove each of the following elements by a preponderance of the evidence:

(1) Defendants willfully acquired or maintained monopoly power by engaging in anticompetitive conduct;[165] and

(2) Defendants' conduct occurred in or affected interstate or foreign commerce.

As I instructed you earlier, you must take as established that Defendants had monopoly power in the market for memantine hydrochloride. You must also take it as established that Defendants' conduct occurred in interstate commerce.[166]

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[165] ABA MODEL INSTRUCTIONS, Ch. 2, Instruction A-1. *See Lidoderm MTD Order*, 74 F. Supp. 3d at 1076 ("A claim of monopoly has two elements: (i) monopoly power; and (ii) unlawful acts.").

[166] *See* Forest Defendants' Answer to Direct Purchaser Plaintiffs' First Amended Class Action Complaint, ECF No. 107 (Sept. 27, 2016) ("Forest admits, for the purposes of this litigation, that it made sales in interstate commerce.").

Jury Instruction 58. Monopolization: Reverse Payment Claim: Element 1: Maintenance of Monopoly Power Through Anticompetitive Conduct

As to the reverse payment theory, you need only determine if Defendants' agreement with Mylan constituted anticompetitive conduct. To determine whether that agreement was anticompetitive, you should follow the instructions I already gave you to determine whether or not that agreement constituted an unreasonable restraint of trade, and answer Question 1 on the verdict sheet.

3. Sherman Act Section 2: Monopolization: Unlawful Maintenance of Monopoly Power by Conversion of the Namenda Market from IR to XR Formulation ("Hard Switch" Claim)

Jury Instruction 59. Defendants' Liability for Monopolization by Hard Switch Product Hop: Defendants Are Estopped From Contesting Their Conduct Was Unlawful

As to the hard switch product hop theory, I instruct you that Defendants' plan to stop selling Namenda IR and withdraw it from the market, and Defendants' announcement and publicizing of that plan in order to convert the market from Namenda IR to Namenda XR, which is referred to as the "hard switch product hop," violated the antitrust laws, specifically Section 2 of the Sherman Act. The Defendants had monopoly power until generics entered in July 2015 as I have explained. I instruct you further that Defendants' hard switch product hop was coercive and anticompetitive; and Defendants had no non-pretextual procompetitive justification for their illegal conduct. These issues were already decided in a prior lawsuit brought by the New York Attorney General and Defendants are not permitted to dispute them again.[167] Therefore, you do not need to make any findings on these issues of fact. The only issues for you to decide concerning the hard switch product hop are the fact and amount of Plaintiffs' damages. Skipping ahead on the verdict sheet for a minute, this is addressed in Question 4, which asks: "What (if any) overcharge damages of the Direct Purchaser Class were caused by the unlawful hard switch product hop alone?" You must answer Question 4 regardless of how you answer the other questions. And notice that it is asking about the hard switch product hop "alone". There is another place on the verdict sheet, in Question 5 that I will come to, that asks what are the total overcharge damages from the hard switch product hop plus the challenged agreement between Defendants and Mylan.

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[167] *Namenda IV*, 2017 WL 4358244, at *16 ("Plaintiffs' motion for collateral estoppel on these issues of fact is GRANTED. They will be presented to the jury as already decided.")

My decision about the hard switch product hop adopted the findings of one of my fellow judges on this Court, Judge Sweet, as well as the U.S. Court of Appeals for the Second Circuit, which granted the New York Attorney General's request for an injunction that barred Defendants from ultimately withdrawing Namenda IR from the market prior to the entry of generic competition,[168] was based on the following findings, which I instruct you to accept as already decided:

- As of December 2014, "Forest had *already* caused anticompetitive injury to the memantine market that had to be rectified."[169]
- As a result of Defendants' "hard-switch" a "significantly higher" number of patients converted from Namenda IR to Namenda XR than if Forest had not attempted to pull Namenda IR from the market.[170]
- Forest's own internal projections estimated that, using only soft-switch tactics, only 30% of Namenda's IR patients would voluntarily switch to Namenda XR. In contrast, under a "hard-switch" strategy, that percentage skyrocketed to 80-100%. Judge Sweet determined that, if the hard switch were allowed to continue, generic competition would only be able to capture 19% of the memantine market, while Forest would continue to control 81% of that market. Forest estimated that the hard

[168] *See New York v. Actavis, PLC*, No. 14 cv-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014) (Sweet, J.); *Namenda II*, 787 F.3d 638 (2d Cir. 2015).
[169] *Namenda IV*, 2017 WL 4358244, at *16.
[170] *Id.* at *12.

switch would result in more than $1 billion in additional sales of Namenda XR as compared to the soft switch.[171]

- As of the time Judge Sweet issued the preliminary injunction in December 2014, Forest's hard switch tactics had *already* resulted in more customers converting from Namenda IR to Namenda XR than Forest had estimated would convert voluntarily. Specifically, at the time the preliminary injunction was issued in December 2014, about 50% of existing patients had converted form Namenda IR to Namenda XR in anticipation of the lack of availability of Namenda IR. This was significantly more than the 30% that Forest had estimated would convert if only soft-switch tactics were employed.[172]
- Forcing patients to switch to Namenda XR would prevent generic substitution because generic versions of IR are not rated by the FDA as bioequivalent to Namenda XR. Defendants' own internal predictions estimated that the hard-switch would successfully convert 80-100% of IR patients to XR prior to generic entry, leaving few to no Namenda IR prescriptions left for which generics would be able to compete. Because Defendants' "forced switch" through something other than competition on the merits has the effect of significantly reducing usage of rivals' products and hence protecting their own monopoly, it is anticompetitive. [173]

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[171] Unredacted Memorandum Decision and Order Granting in Part and Denying in Part Plaintiffs' Motion for Collateral Estoppel and Partial Summary Judgment on Count One; Denying Plaintiffs' and Defendants' Motions for Partial Summary Judgment on Count Five at 33, *In re Namenda Direct Purchaser Antitrust Litig*., No. 15-cv-7488 (CM), at 24-45 (S.D.N.Y. May 23, 2017) (McMahon, J.) (sealed version) ("*Namenda IV (sealed version)*").

[172] *Id.* at 25.

[173] *Namenda II*, 787 F.3d at 655. *See also Namenda IV*, 2017 WL 4358244 at *12 ("Ultimately, if the hard switch continued, it 'would likely have anticompetitive and exclusionary effects on

- Defendants had monopoly power in the relevant market, which here is the market for memantine hydrochloride.[174]

competition in the memantine market, creating a 'dangerous probability' that [Defendants] would maintain [their] monopoly power after generics enter[ed] the market.'" (internal citations omitted).

[174] *Namenda IV*, 2017 WL 4358244, at *10, *16.

C. Causation

1. Causation Generally

Jury Instruction 60. Elements of Causation[175]

If you find that Defendants' conduct violated the Sherman Act through the reverse payment, then you must decide if Plaintiffs were injured by that conduct. As I explained to you, Defendants hard switch product hop violated the Sherman Act, but you must still find whether the hard switch product hop caused Plaintiffs injury. The injury that Plaintiffs allege is an overcharge; in other words they allege that they and the Class paid more than they would have but for Defendants' conduct, either but for the allegedly unlawful reverse payment, or but for the unlawful hard switch product hop, or both.

In order to demonstrate that Plaintiffs were injured, it must be proven that:

(1) Plaintiffs were in fact injured as a result of Defendants' violation of the antitrust laws; and

(2) Defendants' illegal conduct was a material cause of Plaintiffs' injury.[176]

In order to establish "injury in fact," it must be established that Plaintiffs were injured as a result of Defendants' violation of the antitrust laws. Proving the fact of damage does not require Plaintiffs to prove the dollar value of their injury. It requires only that it be established that they in fact suffered an injury as a result of Defendants' antitrust violation. Plaintiffs have been injured if you find that they paid inflated prices for any form of memantine hydrochloride as a result of

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[175] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction A-1.

[176] *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97 (2d Cir. 2017) ("An antitrust plaintiff must show that a defendant's anticompetitive act was a 'material' and 'but-for' cause of plaintiff's injury, although not necessarily the sole cause.") (citing *In re Publ'n Paper Antitrust Litig*., 690 F.3d 51, 65-66 (2d Cir. 2012)).

Defendants' antitrust violation, including if they paid more for branded Namenda than they would have paid for generic Namenda, and that they would have purchased some amount of the less expensive generic in place of the more expensive brand Namenda but for Defendants' conduct, and, with respect to the alleged delay in generic competition, that they paid more for generic Namenda than they otherwise would have.[177]

It must also be established that Defendants' conduct was a material cause of Plaintiffs' injury. This means that some damage occurred to Plaintiffs as a result of Defendants' antitrust violation, and not some other cause. It is not required that Defendants' antitrust violation be the sole cause of Plaintiffs' injury; nor do all other possible causes of injury need to be eliminated. Fact of injury is demonstrated if the antitrust violation was merely a material cause of Plaintiffs' injury.[178]

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[177] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction A-2.

[178] *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969) ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury"); *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 66 (2d Cir. 2012) ("an antitrust defendant's unlawful conduct need not be the sole cause of the plaintiffs' alleged injuries; to prove a 'causal connection' between the defendant's unlawful conduct and the plaintiff's injury, the plaintiff need only 'demonstrate that [the defendant's] conduct was a substantial or materially contributing factor' in producing that injury.") (quoting *Litton Sys., Inc. v. AT&T Co.*, 700 F.2d 785, 823 n. 49 (2d Cir. 1983)); *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97 (2d Cir. 2017) (defendant's anticompetitive act need not be "sole cause" of plaintiffs' injury); *Namenda V*, 331 F. Supp. 3d at 179 ("[P]laintiffs do not have to prove that the unlawful activity that the defendants allegedly engaged in was the sole cause of their injuries. Plaintiffs meet their burden if they show that the defendants' unlawful facts substantially contributed to their injuries, even though other facts may have contributed significantly. An antitrust plaintiff is not required to show that the defendants' acts were a greater cause of the injury than other factors. Plaintiffs need only show that their injury to some degree resulted from defendants' violation.") (quoting *U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1377 (2d Cir. 1988)); *Namenda IV*, 2017 WL 4358244at *16 ("plaintiff need only show that the illegal conduct 'was a substantial or materially contributing factor' to its injuries.") (citing *Litton*).

Concrete and detailed proof is not required.[179] Here, if an antitrust violation is established, you may presume that the Plaintiffs suffered an antitrust injury.[180] The burden is upon the defendant "to bring in evidence tending to rebut the strong inference, arising from the [injury], that the [unlawful act] was in fact a but-for cause of the plaintiff's injury."[181]

Plaintiffs claim they were injured by both the reverse payment to Mylan and the hard switch product hop from Namenda IR to Namenda XR. I will instruct you first how to determine whether the reverse payments caused Plaintiffs' any injury and will then instruct you how to determine whether the hard switch product hop caused Plaintiffs' any injury.

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[179] *Zenith Radio*, 395 U.S. at 123 (recognizing "practical limits" on the burden of proving antitrust injury; proving what would have happened is "rarely susceptible of the kind of concrete, detailed proof of injury which is available in other contexts. The Court has repeatedly held that in the absence of more precise proof, the factfinder may 'conclude as a matter of just and reasonable inference from the proof of defendants' wrongful acts and their tendency to injure plaintiffs' business, and from the evidence of the decline in prices, profits and values, not shown to be attributable to other causes, that defendants' wrongful acts had caused damage to the plaintiffs").

[180] *See Actos End-Payor Antitrust Litig*., 848 F.3d at 101 ("an antitrust plaintiff may be entitled to a presumption of causation where the anticompetitive conduct 'is deemed wrongful because it is believed significantly to increase the risk of a particular injury' and that injury occurred.") (quoting *Publ'n Paper*, 690 F.3d at 66); *Publ'n Paper*, 690 F.3d at 66 ("There is a causal link between an act or activity and an injury when we conclude on the basis of the available evidence that the recurrence of that act or activity will increase the chances that the injury will also occur. In other words, if an act is deemed wrongful because it is believed significantly to increase the risk of a particular injury, we are entitled—in the tort context at least—to presume that such an injury, if it occurred, was caused by the act.") (internal quotes and citation omitted); *Hasbrouck v. Texaco, Inc.*, 842 F.2d 1034, 1042 (9th Cir. 1987) (causation my be "inferred from circumstantial evidence [where] the injury involved was 'precisely the type of loss that the claimed violations of the antitrust laws would be likely to cause[.]'") (quoting *Zenith Radio*, 395 U.S. at 125). Cf. *Actavis*, 570 U.S. 156 ("An unexplained large reverse payment itself would normally suggest … that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market — the very anticompetitive consequence that underlies the claim of antitrust unlawfulness. * * * [T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.").

[181] *Publ'n Paper*, 690 F.3d 51, 67 (2d Cir. 2012).

2. Plaintiffs' Causation Contentions: Injury Caused by the Reverse Payment

Jury Instruction 61. Injury Caused by the Reverse Payment: Delayed Generic Entry

If you answer "Yes" to Question 1, you go to Question 2 of the verdict form. Question 2 asks: "Without the reverse payment, would any generic version of Namenda IR have been launched before July 11, 2015?" In other words, did the reverse payments to Mylan delay the launch of any generic version of Namenda IR, including an authorized generic version Namenda IR? Was the reverse payment a material cause of the delay of Mylan's generic Namenda IR, the generic Namenda IR of another generic manufacturer, and/or Defendants' authorized generic Namenda IR? In answering Question 2, recall that Defendants' unlawful conduct need not be the sole cause of delay, so long as the unlawful conduct was a contributing factor to the delay and hence the injuries of Plaintiffs and the Class.

Also recall that if you find that Forest entered into an anticompetitive reverse payment agreement with Mylan, then you may presume that that anticompetitive agreement caused a delay in the market entry of less-expensive generic versions of Namenda IR.[182] In light of this presumption, the Defendants have the burden of proving by a preponderance of the evidence that the reverse payment agreement was not a material cause of such a delay.

If you answer "Yes" to Question 2, and you must then answer Question 3, which asks: "Which companies would have launched a generic (or authorized generic) version of Namenda IR before July 11, 2015, and if so, when?" The verdict form then includes a list of companies that Plaintiffs allege would have launched a generic version of Namenda IR. The list on the verdict sheet starts with Mylan, the company that allegedly received the reverse payment from Defendants.

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[182] *See Actos End-Payor Antitrust Litig.*, 848 F.3d at 101.

For Mylan, you mark "Yes" in answering Question 3 if you find it would have launched generic Namenda IR before July 11, 2015, and you mark it "No" if you find it would not have launched earlier. If you have marked "Yes", you then fill in the approximate date (month and year) when Mylan would have launched its generic. After Mylan, the verdict sheet doesn't name a company, but says "Authorized Generic." This is asking whether Defendants would have launched an authorized generic and if so, approximately when. You do not need to identify the particular company that would have sold such an authorized generic on behalf of Defendants. You then go down the list of other companies in Question 3: Dr. Reddy's, Lupin, and Sun, presented in alphabetical order.

If you are answering Question 3 – meaning you have answered "Yes" to both Questions 1 and 2 – be sure to fill in an answer for each company listed in Question 3 and the one asking about an authorized generic. Do not leave any blank.

Jury Instruction 62. Injury Caused by the Reverse Payment: Plaintiffs' Contentions in Detail

Plaintiffs assert that the evidence shows that earlier generic entry would have occurred in one of two ways had Defendants not made a reverse payment to Mylan.

First, Plaintiffs say that if Defendants had not reached a settlement with a reverse payment, Defendants would have reached an alternate settlement with Mylan with an earlier generic entry date because it was in their mutual, profit-maximizing interests to settle in this way rather than keep litigating. Under such a settlement, and after a launch by Mylan, certain other generic manufacturers would have also launched their respective generic Namenda IR products pursuant to provisions included in their own settlement agreements (called "Contingent Launch Provisions"), and/or Forest would have launched an authorized generic Namenda..

Second, if Defendants and Mylan did not reach such an alternative settlement, Plaintiffs assert that the evidence shows that Mylan would have ultimately won the patent litigation that Defendants had brought against it concerning Mylan's generic Namenda ANDA in or around June 2012, and would have launched its generic Namenda IR thereafter (and earlier than July 2015). After such a litigation victory by Mylan, Plaintiffs assert that certain other generic manufacturers would have also launched their respective generic Namenda products pursuant to the Contingent Launch Provisions included in their own settlement agreements, and Forest would have launched an authorized generic Namenda.

It is your responsibility to determine what would have happened absent the reverse payment.

1. Alternative Settlement. Plaintiffs' first theory is that, had Defendants not made the reverse payments to Mylan, Defendants and Mylan would have negotiated a settlement with an earlier entry date for Mylan's generic Namenda IR.[183]

In considering whether Forest and Mylan would have reached an alternative settlement, and in considering the reasonably probable entry date for Mylan's generic Namenda IR under that settlement, you must assume that Forest and Mylan are rational companies and that they would have acted to maximize their respective profits.[184] You should disregard any argument that Forest and Mylan would not have acted consistently with their economic interests.[185]

2. Mylan Litigation Victory. Plaintiffs' second theory for how earlier generic entry would have occurred had Defendants not made a reverse payment to Mylan is that, if for some reason Forest and Mylan were unable to agree on an alternative settlement without a reverse payment, Mylan would have ultimately won the patent litigation that Forest brought against it.[186]

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[183] *See Namenda V*, 331 F. Supp. 3d at 200-01 (denying summary judgment as to this theory).

[184] *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981) ("economic rationality must be assumed for all competitors"); *Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985) (holding that the plaintiff "must presume the existence of rational economic behavior" in a "hypothetical free market" absent "the anticompetitive activity. . . . This includes a rational price differential between [the plaintiff's] prices and defendants' prices based on all competitors['] attempts to maximize their own profits, and the potential entry of other competitors into the market.") (citations and footnote omitted).

[185] *See Lidoderm SJ Order*, 296 F. Supp. 3d. at 1179 (holding that "only opinions that are economically rational may be provided").

[186] *See Namenda V*, 331 F. Supp. 3d at 200-01 (denying summary judgment as to this theory).

3. Plaintiffs' Causation Contentions: Injury Caused by the Hard Switch Product Hop

Jury Instruction 63. Injury Caused by the Hard Switch Product Hop

Plaintiffs allege that they were also harmed by Defendants' illegal hard switch product hop from Namenda IR to Namenda XR.

Plaintiffs claim that the hard switch product hop enabled Defendants to achieve more sales of branded Namenda XR than they would have gotten absent the hard switch product hop, and because branded Namenda XR sales were higher, there were lower sales of less expensive generic Namenda IR when the generic entered in July 2015 because generic Namenda IR could not be automatically substituted at pharmacies for branded Namenda XR. Plaintiffs allege that without the illegal hard switch product hop, the conversion of sales from Namenda IR to Namenda XR would have been lower, and therefore there would be more branded Namenda IR sales to be substituted with less expensive generic Namenda IR when the generic became available.

As I mentioned, Question 4 of the verdict form asks: "What (if any) overcharge damages of the Direct Purchaser Class were caused by the unlawful hard switch product hop alone?" In answering Question 4, you must put aside the reverse payment allegations and the challenged agreement between Defendants and Mylan, and assume generic entry occurred when it did in July 2015. Question No. 4 asks you to compute the damages, if any, sustained by Plaintiffs and the Class as a result of Defendants' hard switch product hop only. As I explained to you, the hard

switch product hop was unlawful, and so must determine whether the hard switch product hop was a material cause of injury to Plaintiffs and the Class,[187] and determine the damages from it.[188]

You must answer Question 4 no matter how you answer the other questions.

In answering this question, recall that Defendants' unlawful conduct need not be the sole cause of any injury to Plaintiffs and the Class, so long as the unlawful conduct was a contributing factor to the injuries of the Plaintiffs and the Class. Thus, you may find that Plaintiffs and the Class were injured by the hard switch product hop even if you find that other factors (including Defendants' conduct pre-dating February 14, 2014) also contributed to any injuries.[189] Likewise, Plaintiffs and the Class may recover for injuries sustained after Defendants' unlawful conduct ended, so long as that unlawful conduct was a material cause of such injuries.[190]

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[187] *Zenith Radio*, 395 U.S. at 114 n.9 ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury"); *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 66 (2d Cir. 2012) ("an antitrust defendant's unlawful conduct need not be the sole cause of the plaintiffs' alleged injuries; to prove a 'causal connection' between the defendant's unlawful conduct and the plaintiff's injury, the plaintiff need only 'demonstrate that [the defendant's] conduct was a substantial or materially contributing factor' in producing that injury.") (quoting *Litton Sys., Inc. v. AT&T Co*., 700 F.2d 785, 823 n. 49 (2d Cir. 1983)); *In re Actos End-Payor Antitrust Litig*., 848 F.3d 89, 97 (2d Cir. 2017) (defendant's anticompetitive act need not be "sole cause" of plaintiffs' injury); *Namenda IV*, 2017 WL 4358244 at *16 ("plaintiff need only show that the illegal conduct 'was a substantial or materially contributing factor' to its injuries.'").

[188] *Zenith Radio*, 395 U.S. at 114 (proof of injury requires only that Plaintiffs suffered "some damage flowing from the unlawful conspiracy."); *In re Visa Check/MasterMoney Antitrust Litig*., 280 F.3d 124, 139 (2d Cir. 2001) (plaintiffs need only demonstrate they made "some purchases at the higher price."), *overruled on other grounds by In re Initial Pub. Offering Sec. Litig.*, 471 F.3d 24 (2d Cir. 2006).

[189] *See Namenda V*, 331 F. Supp. 3d at 179 (permitting Plaintiffs to offer evidence concerning conduct pre-dating February 14, 2014).

[190] *Id.* at 179-80 (permitting Plaintiffs to present evidence of "any lasting impact the anticompetitive conduct had post-injunction"); *In re TFT-LCD (Flat Panel) Antitrust Litig.*, No. C 10-1064 SI, 2013 WL 124347, at *1 (N.D. Cal. Jan. 8, 2013); *King Drug Co. of Florence, Inc. v. Cephalon, Inc*., 309 F.R.D. 195, 205 (E.D. Pa. 2015) (recognizing damages period could extend beyond period of alleged delay; it "takes time for the full effects of generic competition to occur"), *rev'd on other grounds*, *In re Modafinil Antitrust Litig*., 837 F.3d 238 (3d Cir. 2016). *Cf. Roton*

Also recall that since it has already been determined that Forest's hard switch product hop behavior was a violation of the antitrust laws, you may presume that this illegal conduct caused injury to the Plaintiffs.[191] In light of this presumption, the Defendants have the burden of proving by a preponderance of the evidence that the hard switch product hop was not a material cause of such injury to Plaintiffs and the Class.

But, in determining injury and damages from the hard switch product hop, you must take it as established that "the result of the hard switch would be that a 'significantly higher' number of patients would convert from Namenda IR to Namenda XR than if Forest had not attempted to pull Namenda IR from the market,"[192] and that "Forest's own internal projections estimated that, using only soft-switch tactics, only 30% of Namenda IR patients would voluntarily switch to Namenda XR."[193] You must further take it as established that as of December 2014, "Forest's hard-switch tactics had *already* resulted in more customers converting from Namenda IR to Namenda XR than Forest had estimated would convert voluntarily," and that "about 50% of existing patients [had] converted from Namenda IR to Namenda XR in anticipation of the lack of availability of Namenda IR. This is significantly more than the 30% that Forest had estimated would convert if only soft-switch tactics were employed."[194]

Barrier, Inc. v. Stanley Works, 79 F.3d 1112, 1120 (Fed. Cir. 1996) (in a patent infringement case, upholding award of "future price erosion damages" which would be incurred following removal of infringing product from the market).

[191] *See Actos End-Payor Antitrust Litig.*, 848 F.3d at 101.

[192] *Namenda IV*, 2017 WL 4358244 at *12 (citing *New York v. Actavis, PLC*, No. 14 CIV. 7473, 2014 WL 7015198, at *28, 39 (S.D.N.Y. Dec. 11, 2014) ("*Namenda I*"), *aff'd sub nom. New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

[193] *Namenda IV (sealed version)* at 24 (citing *Namenda I*, Unredacted Opinion at 80).

[194] *Namenda IV (sealed version)* at 25 (quoting *Namenda I*, 2014 WL 7015198, at *29) (italics in original).

Further, you must recall that the Class here is comprised of "wholesalers and other direct purchasers," and that Defendants "deal[] with wholesalers, not patients."[195] Accordingly, for Plaintiffs and the Class to establish they were injured or to prove damages, they need not "show that individual patient decisions were the result of [D]efendant[s'] alleged conduct."[196]

Turning to Question No. 5 on the Verdict Form, Question 5 asks you: "What are the total overcharge damages of the Direct Purchaser Class?" In answering this question, you should state the total damages from the reverse payment, if any, and the hard switch product hop, if any, together. I will now instruct you concerning the computation of damages.

[195] *Namenda V*, 331 F. Supp. 3d at 218.
[196] *Id.*

D. Damages

Jury Instruction 64. Damages: Introduction and Purpose

The law provides that Plaintiffs should be fairly compensated for all overpayments that were a direct result or likely consequence of the conduct that you have found to be unlawful and that I have instructed you was unlawful.

Plaintiffs have the burden of proving the amount of damages by a preponderance of the evidence. It is for you to determine the amount of damages that have been proved.[197]

[197] MANUAL OF MODEL CIVIL JURY INSTRUCTIONS FOR THE DISTRICT COURTS OF THE NINTH CIRCUIT (2007 ed.), Instruction 5.1; *see also id*. ("If you find for the plaintiff [on the plaintiff's [specify type of claim] claim], you must determine the plaintiff's damages."); ABA MODEL INSTRUCTIONS, Ch. 6, Instruction B-1 ("You must determine the amount of damages, if any, plaintiff is entitled to recover.").

Jury Instruction 65. Damages: Overcharges[198]

The proper way to calculate the amount of damages owed to the Class is to determine the difference between the prices the Class of direct purchasers actually paid for Namenda XR, Namenda IR, and/or generic Namenda IR and the prices they would have paid had Defendants not engaged in their unlawful conduct. This is referred to as the overcharge. Injury is measured by the full extent of the overcharge. You heard expert testimony about the amount of overcharges and you should evaluate such expert testimony in the way I have instructed. In determining the existence and the extent of Plaintiffs' injuries, you must not consider whether Plaintiffs passed on all or some of the alleged overcharge to their own customers,[199] or whether Plaintiffs otherwise may have benefited by the allegedly illegal conduct.[200] This is because the United States Supreme

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[198] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction B-5.

[199] *See Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481, 494 (1968) (defendant "was not entitled to assert a passing-on defense"); *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 729-30 (1977); *In re Namenda Direct Purchaser Antitrust Litig*., No. 15CIV7488CMJCF, 2017 WL 2693713, at *8 (S.D.N.Y. June 21, 2017) (noting Supreme Court has rejected "pass-on defense"); *In re Air Cargo Shipping Servs. Antitrust Litig.*, No. 06-MD-1775, 2010 WL 4916723, at *2 (E.D.N.Y. Nov. 24, 2010) (same); *In re Buspirone Patent Litig*., 210 F.R.D. 43, 60 (S.D.N.Y. 2002) (same).

[200] *See K-Dur*, 686 F.3d at 223 ("requiring plaintiffs to show that no class member benefitted from the challenged conduct in the form of greater profits is contrary to the Supreme Court's decision in *Hanover Shoe*. In *Hanover Shoe*, the Supreme Court permitted antitrust plaintiffs to seek overcharge damages rather than lost profits damages precisely because proving lost profits was too complicated and burdensome. The same logic applies equally, if not more strongly, in the class certification setting because under defendants' proposed approach, plaintiffs would not only have to assess their own lost profits but also those of potential class members.") (citations omitted); *In re Buspirone Patent & Antirust Litig*., 210 F.R.D. 43, 5860 (S.D.N.Y. 2002) (rejecting argument that drug wholesalers' injury in the form of overcharges would be reduced because they would have "lost much of their marketshare [sic]… such that their overall profits would have decreased" as inconsistent with *Hanover Shoe* and *Illinois Brick*); *Sports Racing Servs., Inc. v. Sports Car Club of Am., Inc.*, 131 F.3d 874, 884-85 (10th Cir. 1997) (rejecting argument that plaintiff benefitted from alleged violation and therefore lacked injury because "[t]hat reasoning is directly contrary to the Supreme Court's holding in *Hanover Shoe*. *Hanover Shoe* precludes the argument that [plaintiff] did not suffer cognizable antitrust injury merely because it passed overcharges on to its customers or otherwise was shielded from competition by the defendants' anticompetitive

Court has ruled that direct purchasers like the Plaintiffs and the Class here in a sense stand in for all purchasers, and direct purchasers are entitled to collect the full amount of overcharges they paid. That is the law you must follow.

As I mentioned earlier, Plaintiffs contend that they were harmed from the hard switch product hop alone, even if the date that generic competition started is unchanged, because some of their purchases of branded Namenda XR would have been branded Namenda IR without the hard switch product hop, and those branded Namenda IR purchases then would have become generic Namenda IR purchases at lower prices after generics entered in July 2015, but for the unlawful hard switch product hop. Here, the overcharges are the difference in price between purchases made of Namenda XR and the price for generic Namenda IR. Question No. 4 asks: "What (if any) overcharge damages of the Direct Purchaser Class were caused by the unlawful hard switch product hop alone?" Again, you must answer this question on the verdict form regardless of your answers to the other questions

Plaintiffs also contend that without the reverse payment, lower priced generic versions of Namenda IR would have entered the market earlier than July 2015. Specifically, Plaintiffs claim that generic entry for Namenda IR would have occurred in June or November 2012 or at some other point earlier than July 2015. As I mentioned earlier, Question No. 5 of the Verdict Form asks you to compute the entire amount of any damages sustained by Plaintiffs and the Class as a result of Defendants' unlawful conduct, the illegal hard switch product and the reverse payments to Mylan.

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behavior"); *Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, 246 F.R.D. 293, 303-04 (D.D.C. 2007); *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 369 (D. Mass. 2004).

Jury Instruction 66. Damages: Standard[201]

As I mentioned, Plaintiffs are proceeding as a Class. The Class is defined as follows:

> All persons or entities in the United States and its territories who purchased branded Namenda IR 5 or 10 mg tablets, and/or generic Namenda IR 5 or 10 mg tablets (including an authorized generic), and/or branded Namenda XR capsules, directly from Forest or its successors in interest, Actavis and Allergan, and/or from any generic manufacturer at any time during the period from June 2012 until September 30, 2015 (the "Class"). Excluded from the Class are the defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

To award damages for the Class, you do not need to determine the overcharge paid by each class member with absolute mathematical certainty or precision. It is sufficient for you to estimate the overcharge paid by class members in the aggregate, as long as the estimate is based on evidence and reasonable inferences.[202] You may not base your damages award on guesswork or speculation.

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[201] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction B-7.

[202] *See Van Gemert v. Boeing Co.*, 553 F.2d 812, 815–16 (2d Cir. 1977) (affirming, in part, award of aggregate damages to plaintiff class of bondholders); *Gerstle v. Gamble–Skogmo, Inc.*, 478 F.2d 1281, 1290, 1310 (2d Cir. 1973) (affirming award of aggregate damages in securities class action); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 197-98 (1st Cir. 2009) ("The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself."); *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 534 (6th Cir. 2008) ("Damages in an antitrust class action may be determined on a classwide, or aggregate, basis, without resorting to fluid recovery where the [evidence] . . . provide[s] a means to distribute damages to injured class members in the amount of their respective damages.") (citation omitted); *Torres v. Mercer Canyons Inc.*, 835 F.3d 1125, 1140 (9th Cir. 2016) (approving of calculating damages on an aggregate basis); *id*. ("There is no requirement in Rule 23 that aggregate damages be calculable, but where they are, they may be all that plaintiffs need to prove.") (quoting William B. Rubenstein, *Newberg on Class Actions* § 12.2 (5th ed.)); *In re Air Cargo Shipping Servs. Antitrust Litig.*, No. 06-MD-1175 JG VVP, 2014 WL 7882100, at *61 (E.D.N.Y. Oct. 15, 2014), *report and recommendation adopted*, No. 06-MD-1775 JG VVP, 2015 WL 5093503 (E.D.N.Y. July 10, 2015) ("Courts have commonly accepted the calculation of average damages in antitrust cases"); *id.* (allowing computations of average class overcharges to compute aggregate damages); *In re Nexium (Esomeprazole) Antitrust Litig.*, 297 F.R.D. 168, 182 (D. Mass. 2013) ("The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself.") (quoting *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 197 (1st Cir. 2009)); *In re K-Dur Antitrust Litig.*, No. CIV. A. 01-1652 JAG, 2008 WL 2699390, at *19 (D.N.J. Apr. 14, 2008)

If determining the amount of damages requires you to guess or speculate, you may not award damages. But you may make a just and reasonable estimate of the damages based on relevant data.[203]

(certifying class and rejecting defense attacks on aggregate damage model) , *aff'd*, 686 F.3d 197 (3d Cir. 2012), *cert. granted, judgment vacated sub nom. Merck & Co. v. Louisiana Wholesale Drug Co.*, 570 U.S. 913 (2013), and *Upsher-Smith Labs., Inc. v. Louisiana Wholesale Drug Co.*, 570 U.S. 913 (2013), *reinstatement granted*, No. 10-2077, 2013 WL 5180857 (3d Cir. Sept. 9, 2013); *In re NASDAQ Mkt.-Makers Antitrust Litig.*, 169 F.R.D. 493, 521 (S.D.N.Y. 1996) (approving of use of aggregate damages award).

[203] *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264 (1946) ("[W]here the defendant by his own wrong has prevented a more precise computation, the jury may not render a verdict based on speculation or guesswork. But the jury may make a just and reasonable estimate of the damages based on relevant data, and render its verdict accordingly.").

Jury Instruction 67. Damages: Basis for Calculating Damages[204]

Defendants "may not benefit from any uncertainty concerning damages [their] own wrongful conduct has caused."[205] However, the amount of damages must have a reasonable basis in the evidence and must be based on reasonable, non-speculative assumptions and estimates. Plaintiffs must prove the reasonableness of each of the assumptions upon which the damages calculation is based.

Plaintiffs are entitled to recover for such injury that was the direct result or likely consequence of the unlawful acts of Defendants. If you find that Plaintiffs' injuries were caused in part by Defendants' alleged antitrust violation and in part by other factors, then you may award damages only for that portion of Plaintiffs' alleged injuries that were caused by Defendants' violation.[206] However, Plaintiffs do not need to be precise in allocating the effects of Defendants'

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[204] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction B-3; *see also id*., Note 2 ("The Supreme Court has recognized that '[t]he vagaries of the marketplace usually deny us sure knowledge of what plaintiff's situation would have been in the absence of defendant's antitrust violation.' *J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 566 (1981) (standards of proving damages can be relaxed, but declining to apply relaxed standards in light of weakness of the evidence and instead remanding). Accordingly, 'a lightened burden of proof is imposed on a plaintiff seeking to prove antitrust damages once violations of the law have been established.' *Reid Bros. Logging Co. v. Ketchikan Pulp Co.*, 699 F.2d 1292, 1299 (9th Cir. 1983); *Amerinet, Inc. v. Xerox Corp.*, 972 F.2d 1483, 1493, 1495 (8th Cir. 1992) ('[a] treble-damage plaintiff is not required to prove exactly and with total certainty the amount of antitrust damages which it has sustained, if that plaintiff clearly demonstrates that defendant's antitrust violations caused its antitrust injury,' but finding plaintiff failed to carry its burden)."); *id*. Note 2 ("Although there is a relaxed standard of proof as to the amount of damage, the Supreme Court has made clear that a damage award may not be based on 'speculation or guesswork.' *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264 (1946) ('[E]ven where defendant by his own wrong has prevented a more precise computation, the jury may not render a verdict based on speculation or guesswork.')").

[205] *Namenda V*, 331 F. Supp. 3d at 182.

[206] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction B-4.

alleged antitrust violation and other factors.[207] Rather, Plaintiffs need only present a method that attributes damages to some degree to Defendant's illegal conduct.[208]

Plaintiffs and the direct purchaser Class are entitled to recover the full amount of the overcharge as damages, without regard to whether some portion of the overcharge was passed on to their customers.[209]

If you find that Plaintiffs have provided a reasonable basis for determining damages, then you may award damages based on a just and reasonable estimate supported by the evidence. If you find that Plaintiffs have failed to carry their burden of providing a reasonable basis for determining damages, then you may not award damages.

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[207] *Insignia Sys., Inc. v. News Am. Mktg. In-Store, Inc.*, No. CIV 04-4213 JRT/AJB, 2011 WL 167259, at *14 (D. Minn. Jan. 14, 2011) (plaintiff need only present a method to attribute damages to the exclusionary conduct.); *In re High-Tech Employee Antitrust Litig.*, No. 11-CV-02509-LHK, 2014 WL 1351040, at *18 (N.D. Cal. Apr. 4, 2014) (damages model need not "precisely segregate out effects of every possible factor, including legal conduct, that could impact the dependent variable"); *id.* ("[D]amages issues in [antitrust] cases are rarely susceptible of the kind of concrete, detailed proof of injury which is available in other contexts.") (quoting *Zenith*, 395 U.S. at 123).

[208] *U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1378 (2d Cir. 1988) ("damages awarded must be traced to some degree to unlawful acts.").

[209] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction B-1, Notes ("In certain cases it may be appropriate to clarify that the direct purchaser plaintiff is entitled to recover the full amount of the overcharge as damages, without regard to whether some portion of the overcharge was passed on to downstream customers. *See, e.g.*, *Paper Systems v. Nippon Paper Indus. Co.*, 281 F.3d 629, 632-34 (7th Cir. 2002) (citing *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977)).").

Jury Instruction 68. Damages: Joint and Several Liability[210]

Each participant in a conspiracy that violates the antitrust laws is jointly and severally liable for all of the damages resulting from the conspiracy. This means that each conspirator is fully liable for all of the damages caused by the conspiracy and not solely for damages caused by an individual conspirator. I direct you that Defendants are liable for all overcharge damages caused by the conspiracy. Therefore, if you award damages, it will be as a single figure, and you should not concern yourself with allocation of the damages to particular defendants or any potential co-conspirators who are not defendants here.

[210] ABA MODEL INSTRUCTIONS, Ch. 6, Instruction B-17; *see also Beltz Travel Services, Inc. v. International Air Trans. Ass'n*, 620 F.2d 1360, 1367 (9th Cir. 1980) (In antitrust action, "[a]ll conspirators are jointly liable for the acts of their co-conspirators."); *Paper Sys. Inc. v. Nippon Paper Indus. Co.*, 281 F.3d 629, 632 (7th Cir. 2002) ("Nothing in *Illinois Brick* displaces the rule of joint and several liability, under which each members of a conspiracy is liable for all damages caused by the conspiracy's entire output.") (citing *Texas Industries, Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630 (1981)).

E. Deliberations

Jury Instruction 69. Duty to Deliberate

The verdict must represent the considered judgment of each of you. In order to return a verdict, it is necessary that each juror agree. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another, and to deliberate with a view to reaching an agreement, if you can do so without disregard of individual judgment. You must each decide the case for yourself, but only after an impartial consideration of the evidence in the case with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views, and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence, solely because of the opinion of your fellow jurors, or for the mere purpose of returning a verdict.

Remember at all times that you are judges—judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

3 FED. JURY PRAC. & INSTR. § 106:01 (6th ed.)

Jury Instruction 70. Election of Foreperson; Duty to Deliberate; Communications with Court; Cautionary; Unanimous Verdict; Verdict Form

You must follow these rules while deliberating and returning your verdict:

First, when you go to the jury room, you must select a foreperson. The foreperson will preside over your discussions and speak for you here in court.

Second, it is your duty, as jurors, to discuss this case with one another in the jury and try to reach agreement.

Each of you must make your own conscientious decision, but only after you have considered all the evidence, discussed it fully with the other jurors, and listened to the views of the other jurors.

Do not be afraid to change your opinions if the discussion persuades you that you should. But do not make a decision simply because other jurors think it is right, or simply to reach a verdict. Remember at all times that you are judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

Third, if you need to communicate with me during your deliberations, you may send a note to me through the marshal or bailiff, signed by one or more jurors. I will respond as soon as possible either in writing or orally in open court. Remember you should not tell anyone—including me—how your votes stand numerically.

Fourth, your verdict must be based solely on the evidence and on the law I have given to you in these instructions. The verdict must be unanimous. Nothing I have said or done is intended to suggest what your verdict should be—that is entirely for you to decide.

Finally, the verdict form is simply the written notice of the decision that you reach in this case. Throughout these instructions, I have explained how to complete the form of verdict. You will take this form to the jury room, and when each of you has agreed on the verdict[s], your foreperson will fill in the form, sign and date it, and advise the marshal or bailiff that you are ready to return to the courtroom.

3 FED. JURY PRAC. & INSTR. § 103:50 (6th ed.)

Jury Instruction 71. Verdict Forms—Jury's Responsibility

Nothing said in these instructions and nothing in any verdict form prepared for your convenience is meant to suggest or convey in any way or manner any suggestion or hint as to what verdict I think you should find. What the verdict shall be is your sole and exclusive duty and responsibility.

3 FED. JURY PRAC. & INSTR. § 106:07 (6th ed.)

Jury Instruction 72. Communications Between Court and Jury During Jury's Deliberations

If it becomes necessary during your deliberations to communicate with me, you may send a note by a bailiff, signed by your foreperson or by one or more members of the jury. No member of the jury should ever attempt to communicate with me by any means other than a signed writing. I will never communicate with any member of the jury on any subject touching the merits of the case otherwise than in writing, or orally here in open court.

From the oath about to be taken by the bailiffs you will note that they too, as well as all other persons, are forbidden to communicate in any way or manner with any member of the jury on any subject touching the merits of the case.

Bear in mind also that you are never to reveal to any person—not even to me—how the jury stands, numerically or otherwise, on the questions before you, until after you have reached a unanimous verdict.

3 FED. JURY PRAC. & INSTR. § 106:08 (6th ed.)

Dated: April 30, 2019

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